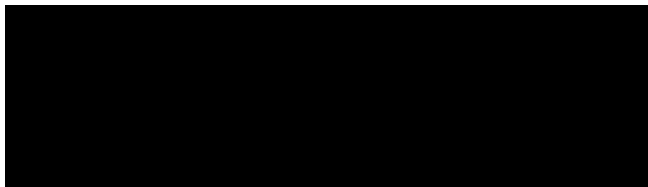


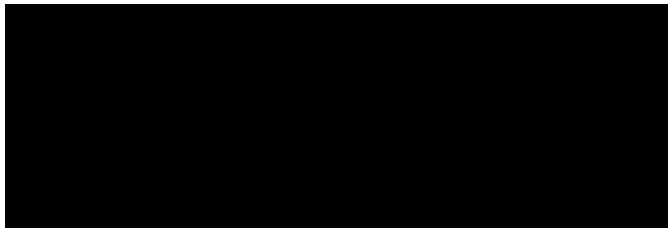
FINAL REPORT
LEAFLET READABILITY TEST FOR THE MEDICINAL PRODUCT PROMAZINE HYDROCHLORIDE 25MG/5ML & 50MG/5ML ORAL SYRUP

STUDY SPONSOR: Aristo Pharma GmbH
Wallenroder straÙe 8-10
13435 Berlin · Germany

CRO:  S.L.



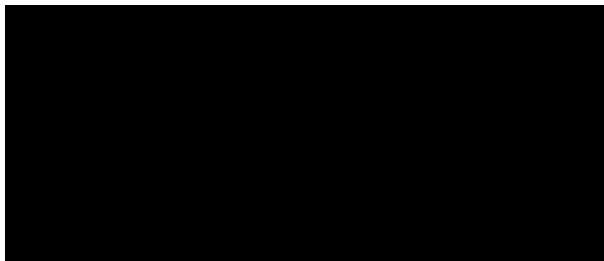
**PRINCIPAL
INVESTIGATOR:**



Reference of the study: 

Date: 07/2022

Version: 0



1. ABSTRACT

Study	Readability test of leaflet
Name of the study	Readability user test of leaflet for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup
Code	[REDACTED]
Study sponsor	Aristo Pharma GmbH Wallenroder straÙe 8-10 13435 Berlin · Germany
Responsible for monitoring	[REDACTED] S.L. [REDACTED] [REDACTED] [REDACTED]
Principal Investigator	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
Location of the study	[REDACTED] S.L. [REDACTED] [REDACTED]
Objective of the study	Evaluate the readability of the leaflet for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup.
Volunteers	Sample size: 23 subjects. Inclusion criteria: ➤ Participants of both genders (men and women). ➤ Older than 18 years. ➤ Adequate cultural level and understanding of the study. ➤ Good understanding of English. ➤ Agree to participate voluntarily in the study and to give a written informed consent. ➤ Participants who could potentially use the medicinal product whose leaflet is under evaluation.

	Exclusion criteria: ➤ Blind people. ➤ Training in medicine or health sciences (doctors, nurses, pharmacists, healthcare professionals in general...) ➤ Difficulties understanding English.														
Development of the study	<table> <tr> <th>Phases</th><th>Estimated time</th></tr> <tr> <td>1. Preparation of the questionnaire, the answer sheet and the protocol. Shipment to the sponsor for approval.</td><td>0.5 weeks</td></tr> <tr> <td>2. Recruitment and pilot interviews with 3 subjects (Pilot phase). Report and proposal of changes, according to the results.</td><td>1 week</td></tr> <tr> <td>3. Recruitment and interviews with a first group of 10 subjects (1st Phase). Analysis and evaluation.</td><td>1 - 2 weeks</td></tr> <tr> <td>4. Recruitment and interviews with a second group of 10 subjects (2nd Phase). Analysis and evaluation.</td><td>1 - 2 weeks</td></tr> <tr> <td>5. Final report.</td><td>0.5 - 1 week</td></tr> <tr> <td>TOTAL</td><td>4 - 6.5 weeks</td></tr> </table>	Phases	Estimated time	1. Preparation of the questionnaire, the answer sheet and the protocol. Shipment to the sponsor for approval.	0.5 weeks	2. Recruitment and pilot interviews with 3 subjects (Pilot phase). Report and proposal of changes, according to the results.	1 week	3. Recruitment and interviews with a first group of 10 subjects (1st Phase). Analysis and evaluation.	1 - 2 weeks	4. Recruitment and interviews with a second group of 10 subjects (2nd Phase). Analysis and evaluation.	1 - 2 weeks	5. Final report.	0.5 - 1 week	TOTAL	4 - 6.5 weeks
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3. Recruitment and interviews with a first group of 10 subjects (1st Phase). Analysis and evaluation.	1 - 2 weeks														
4. Recruitment and interviews with a second group of 10 subjects (2nd Phase). Analysis and evaluation.	1 - 2 weeks														
5. Final report.	0.5 - 1 week														
TOTAL	4 - 6.5 weeks														

Approval	Readability test of leaflet will be considered satisfactory and passed as long as, for each question: ➤ The requested information is correctly located by 90% of the participants. ➤ Of these participants, 90% understand what such information means.
Calendar	Experimental phase: 06/2022 – 07/2022 Final report: 07/2022

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3. GENERAL INFORMATION

3.1. IDENTIFICATION OF THE TEST

TITLE: "Readability test of the leaflet for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup".

CODE OF THE STUDY: [REDACTED]

3.2. TYPE OF TEST

Test to evaluate the leaflet Readability for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup.

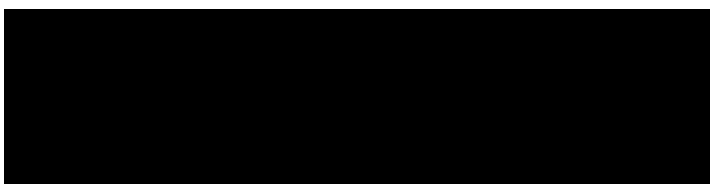
3.3. DESCRIPTION OF THE MEDICINAL PRODUCT

The leaflet evaluated in this readability test is for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup.

It contains promazine hydrochloride which belongs to a group of medicines called phenothiazines.

Promazine can be used to calm your emotions particularly if you feel restless and agitated, particularly if you are an older person.

3.4. LOCATION WHERE THE STUDY IS PERFORMED



3.5. DEVELOPMENT OF THE TEST

According to the "Guideline on the readability of the labelling and package leaflet of medicinal products for human use. Revision 1, 12 January 2009", the test must be carried out following the phases set out below.

1. Preparation of questionnaire and protocol. Approval by Aristo Pharma GmbH.
2. Recruitment and implementation of the pilot phase to 3 volunteers.

3. Evaluation of the pilot questionnaires. Report and proposal of changes, according to the results.
4. Recruitment of subjects. First group of interviews (1st Phase): Interviews carried out to 10 volunteers, who are possible target patients of the product under study, of all ages and educational levels.
5. Evaluation of the results.
6. Recruitment of subjects. Second group of interviews (2nd Phase): Interviews carried out to 10 volunteers, who are possible target patients of the product under study, of all ages and educational levels.
7. Evaluation of the results and recommendations for changes in the leaflet.
8. Report for Health Authorities.

All interviews were conducted face-to-face by qualified personnel. The duration of the sessions was approximately 40 minutes. Each questionnaire consisted of 12 questions that the volunteer had to answer within the allocated time, evaluating for each question both the ability to find the information in the leaflet and the ability to understand the answer. Additionally, in the cases in which the researcher considered it appropriate, the oral information added was taken into account to confirm the understanding of the information read.

4. METHODOLOGY AND DEVELOPMENT OF THE STUDY

4.1. INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria

Subjects must meet each and every one of the following criteria to be included in the study:

- ✓ Participants of both genders (men and women)
- ✓ Older than 18 years.
- ✓ Adequate cultural level and understanding of the study.
- ✓ Good understanding of English
- ✓ Agree to voluntarily participate in the test and give a written informed consent.
- ✓ Participants who can potentially take the medicinal product whose leaflet is under evaluation.

Exclusion criteria

The presence of at least one of the following criteria will be grounds for exclusion from the readability test:

- ✓ Blind people.
- ✓ People who have training in medicine or health sciences (doctors, nurses, pharmacists, healthcare professionals in general).
- ✓ People with difficulties understanding English.

4.2. NUMBER OF SUBJECTS AND RECRUITMENT OF THEM

For the correct performance of the study, and according to “Guideline on the readability of the labelling and package leaflet of medicinal products for human use. 1st Revision, 12 January 2009”, the following subjects were recruited in each of the phases:

- Pilot interviews: 3 subjects
- First phase of interviews: 10 subjects
- Second phase of interviews: 10 subjects

Altogether, 23 subjects were recruited to carry out this readability test. Since the medicinal product is indicated for the treatment of a specific or seasonal situation and it is intended for practically any individual, except for very specific medical conditions, a specific population and / or location was not selected.

4.3. PLANNED INTERVENTIONS

For the development of this study, the schedule established in the protocol was followed, trying to adjust to it as much as possible. The key dates were the following:

- 1st interview: 27th June 2022
- End of pilot phase: 29th June 2022
- End of 1st phase: 7th July 2022
- End of 2nd phase: 14th July 2022
- Closure of the database: 15th July 2022
- Final data: 18th July 2022
- Final report: 22nd July 2022

4.4. OBJETIVES OF THE STUDY

The main objective of the study "Readability test of the leaflet for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup" is the evaluation of the Readability and usability of the leaflet prepared for Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup.

To this end, during the different phases of the test, leaflet corresponding to the final version and printing were used.

As described in the "Guideline on the readability of the labelling and package leaflet of medicinal products for human use. Revision 1, 12 January 2009", the leaflet will be considered to satisfy the readability test when, for each question:

- 90% of the volunteers consulted are able to find the information required in the leaflet and,
- of these volunteers, 90% can demonstrate that they understand the information.

4.5. METHODOLOGY

The procedure used was the face-to-face interview for the resolution of the questionnaire, with an approximate duration of 40 minutes for each interview.

This questionnaire consisted of 12 questions in which two aspects were evaluated by the investigator: first, the ability to find the requested information in the leaflet; and second, the individual's ability to understand the answer.

The interviews were conducted individually. For each phase, before starting the test, the investigator gave the volunteer the information sheet and the informed consent. The investigator resolved any doubts that might arise in this regard. Once the subject gave his/her consent, he/she was asked to read the leaflet, and the interviewer asked him/her one by one all the questions, asking him/her to write the answer on the corresponding questionnaire.

In addition, the investigator evaluated the speed and ease of each volunteer in finding the requested information. When the investigator considered it appropriate, the oral information additionally provided was also taken into account to confirm the understanding of the information read.

4.6. DATA PROCESSING

To carry out the data analysis, the statistical package GNU PSPP for Windows version 1.0.1-g818227 was used.

On the one hand, for each of the phases, the sociodemographic characteristics of the population were studied by analysis of means and/or frequencies, including parameters such as age, sex and educational level.

On the other hand, as main objective of the study, the answers to each question (with their sections) were analyzed, through an analysis of the frequencies of each type of answer (correct / incorrect).

The leaflet was considered to satisfy the readability test when, for each question, 90% of the volunteers were able to find the required information on the leaflet and, of these, 90% could demonstrate that they understood the information. That is, at least 81% of the volunteers interviewed were able to locate and understand the information for each question.

5. RESULTS

5.1. PHASE RESULTS

Here below you can find the results of the readability test for Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup, solution, structured by phases: pilot (volunteers 01 to 03), phase 1 (volunteers 01 to 10) and phase 2 (volunteers 01 to 10).

A. PILOT PHASE

I. Characteristics of the target population

Age and gender

For the pilot phase, 3 volunteers were recruited: 2 men and 1 woman. Their ages were between 19 and 44 years old. The average age was 27.67, with a standard deviation of 14.15.

AGE

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido 19	1	33.3%	33.3%	33.3%
20	1	33.3%	33.3%	66.7%
44	1	33.3%	33.3%	100.0%
Total	3	100.0%		

Table 1 Age of the participants in the pilot phase*

**("válido" means "valid", "frecuencia" means "frequency", "porcentaje" means "percentage", "porcentaje válido" means "valid percentage", and "porcentaje acumulado" means "cumulative percentage").*

GENDER

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Man	2	66.7%	66.7%	66.7%
	Woman	1	33.3%	33.3%	100.0%
Total		3	100.0%		

Table 2 Gender of the participants in the pilot phase

Level of Education

The table below summarizes the level of education of the volunteers of the pilot phase. There were 1 participant with High school level or equivalents, 1 participant with Vocational training or equivalents and 1 participant with Bachelor degree.

LEVEL OF EDUCATION

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	High school level or equivalents	1	33.3%	33.3%	33.3%
	Vocational training or equivalents	1	33.3%	33.3%	66.7%
	Bachelor degree	1	33.3%	33.3%	100.0%
Total		3	100.0%		

Table 3 Level of Education of the participants in the pilot phase

Visual disorders

It is also analysed if the participants had visual disorders, such as myopia, astigmatism, hyperopia, presbyopia, etc. Information on whether they wear glasses or contact lenses to overcome the impairments is also available. One of the participants in the pilot phase had visual disorders, specifically myopia, and wear glasses or contact lenses to solve it.

VISUAL DISORDERS

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	NO	2	66.7%	66.7%	66.7%
	YES	1	33.3%	33.3%	100.0%
Total		3	100.0%		

Table 4 Visual disorders of the participants in the pilot phase

II. Results of the readability test

Below are the percentages of hits and mistakes for the 12 questions of the readability test. Each question consists of 2 sections: section "a" determines the ability to locate the answer in the leaflet, and section "b" evaluates the ability to understand the answer given in the leaflet and express it in their own words.

1. What Promazine Syrup used for?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 1A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 5 Results of question 1a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 1B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 6 Results of question 1b, pilot phase (%)

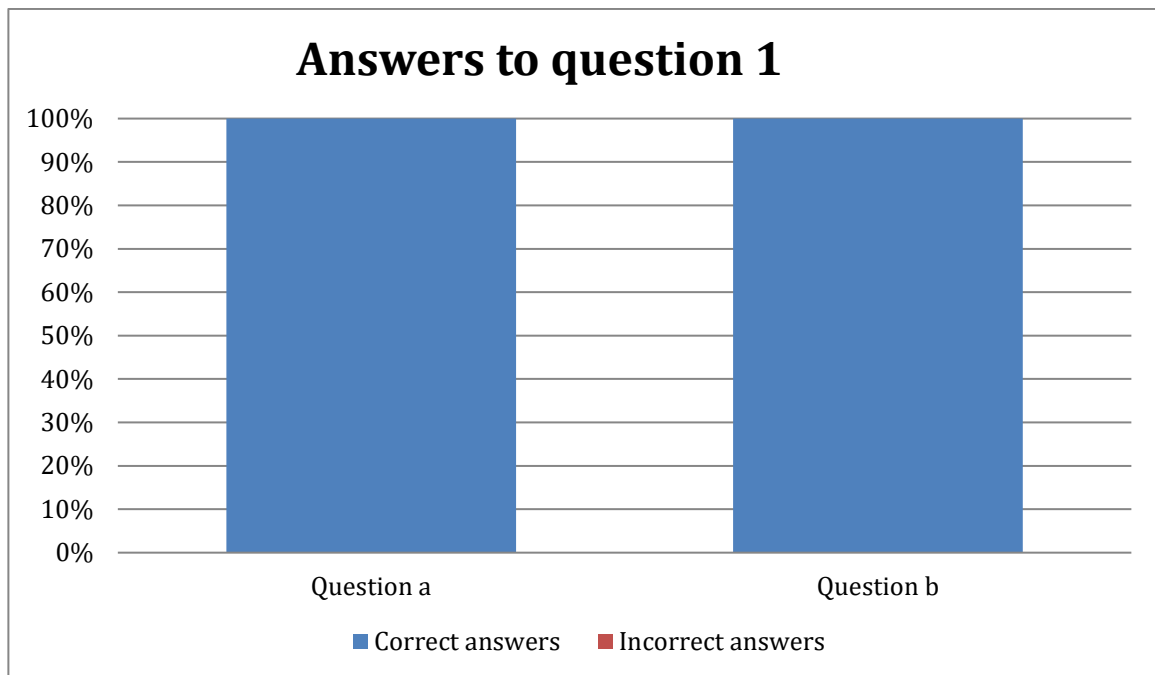


Figure 1 Correct and incorrect answers to question 1, pilot phase (%)

2. Can you take Promazine Syrup if you are allergic to promazine?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 2A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 7 Results of question 2a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 2B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 8 Results of question 2b, pilot phase (%)

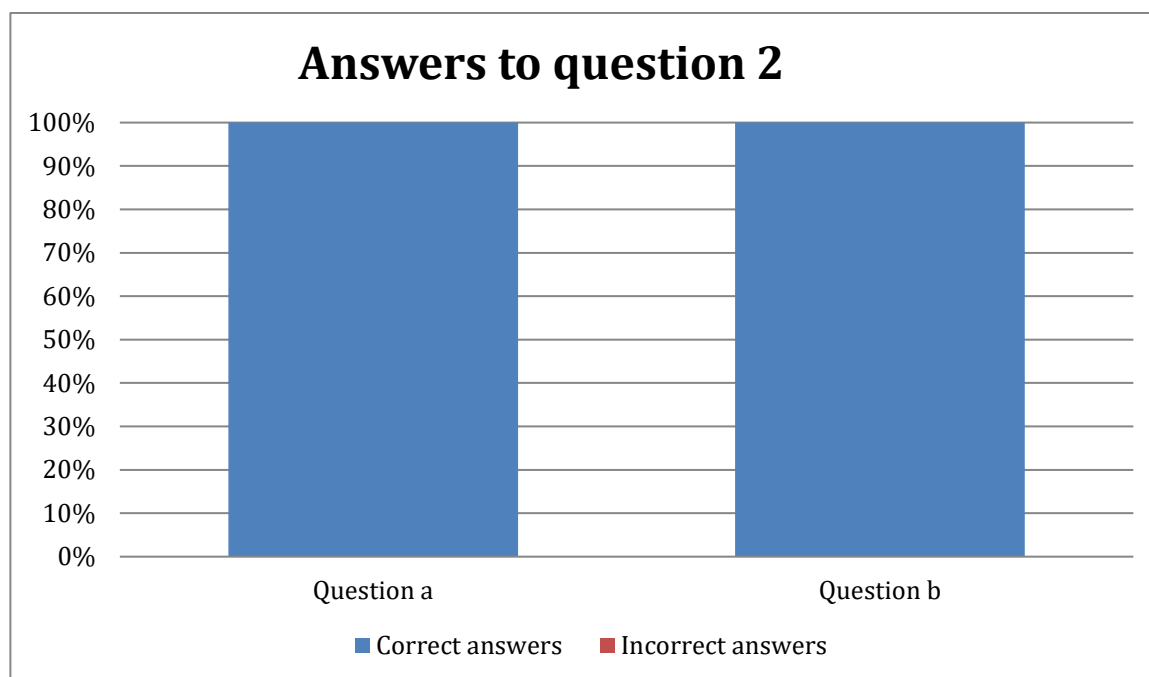


Figure 2 Correct and incorrect answers to question 2, pilot phase (%)

3. Can you take Promazine Syrup if you have bone marrow depression?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 3A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 9 Results of question 3a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 3B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 10 Results of question 3b, pilot phase (%)

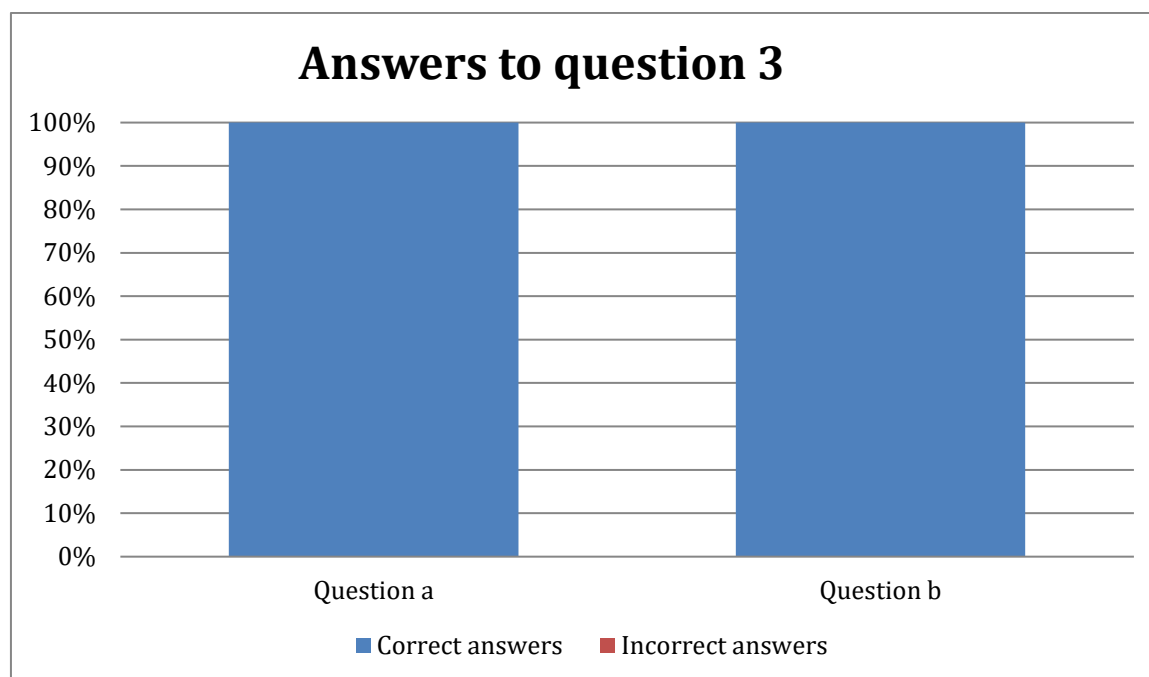


Figure 3 Correct and incorrect answers to question 3, pilot phase (%)

4. Can a patient breast-feed take Promazine Syrup without ask a doctor?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 4A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 11 Results of question 4a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 4B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 12 Results of question 4b, pilot phase (%)

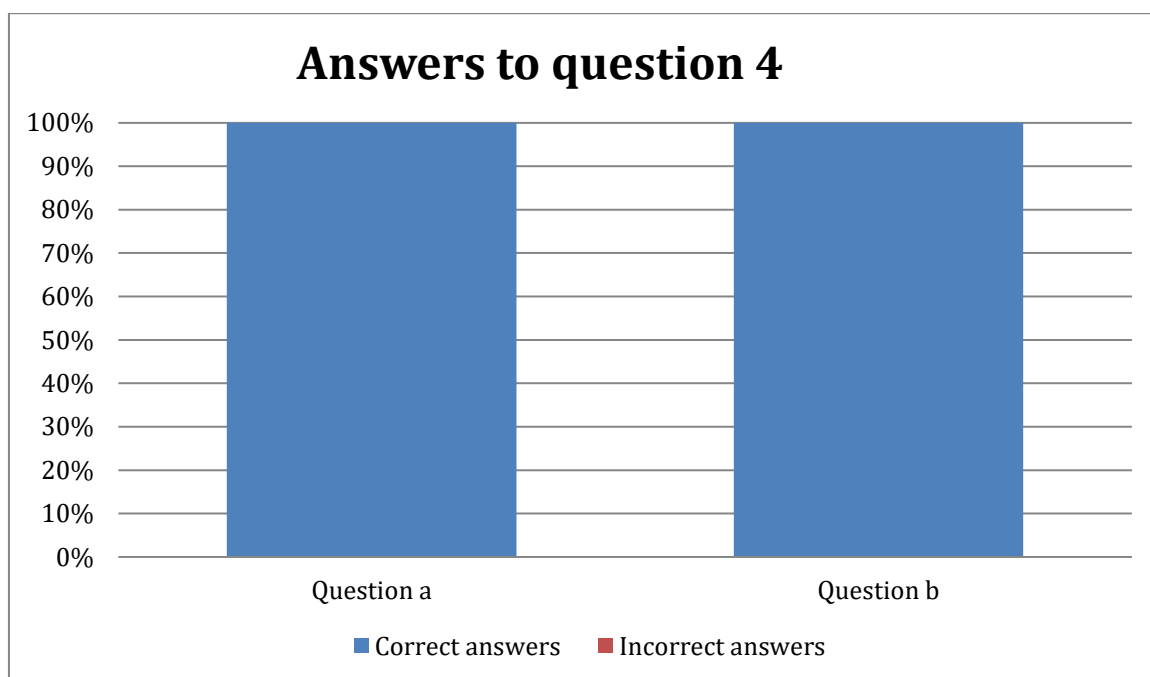


Figure 4 Correct and incorrect answers to question 4, pilot phase (%)

5. What is the recommended dose for Promazine Syrup in adults?
- a) Where can the answer to this question be found in the leaflet?
- 100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 5A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	3	100.0%	100.0%	100.0%
Total		3	100.0%		

Table 13 Results of question 5a, pilot phase (%)

- b) If possible, write in your own words the answer to the question.
- 100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 5B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	3	100.0%	100.0%	100.0%
Total		3	100.0%		

Table 14 Results of question 5b, pilot phase (%)

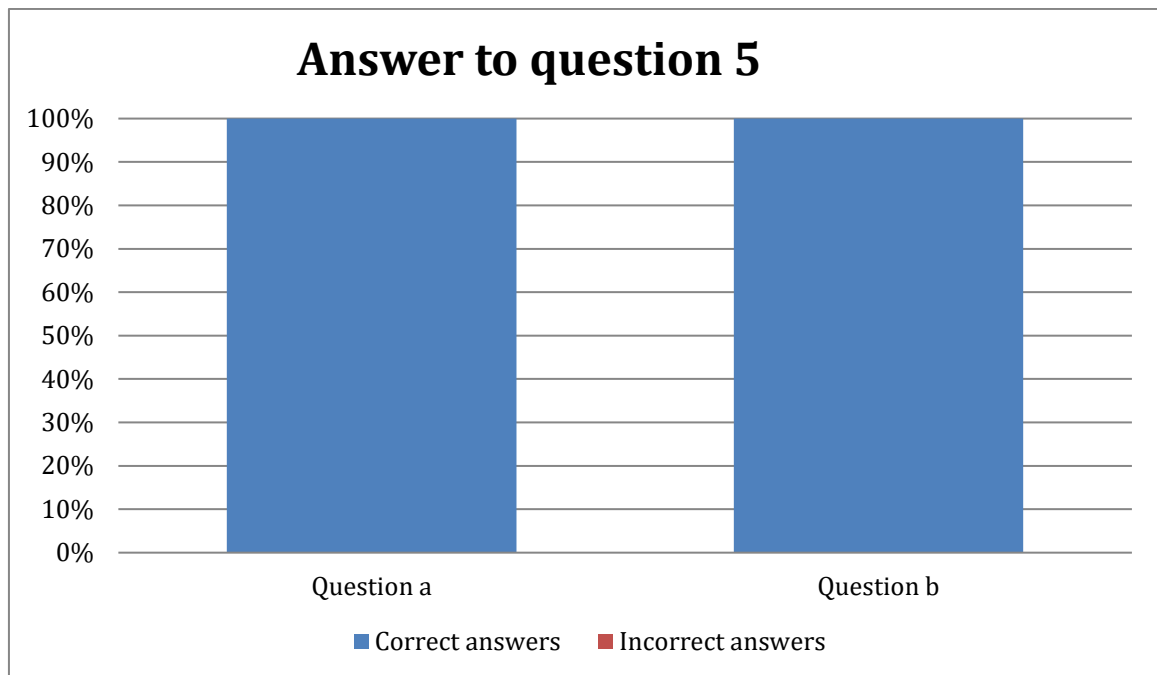


Figure 5 Correct and incorrect answers to question 5, pilot phase (%)

6. Can you drive if you are under Promazine Syrup treatment?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 6A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 15 Results of question 6a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 6B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 16 Results of question 6b, pilot phase (%)

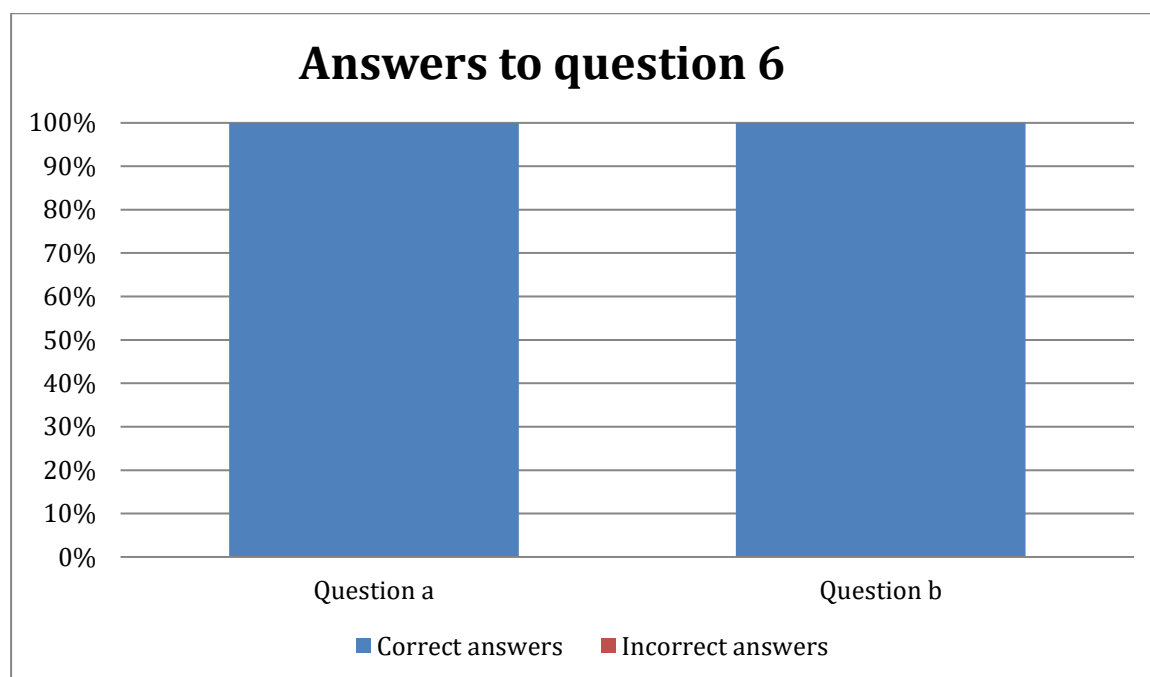


Figure 6 Correct and incorrect answers to question 6, pilot phase (%)

7. Can you take alcohol if you take Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 7A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 17 Results of question 7a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 7B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 18 Results of question 7b, pilot phase (%)

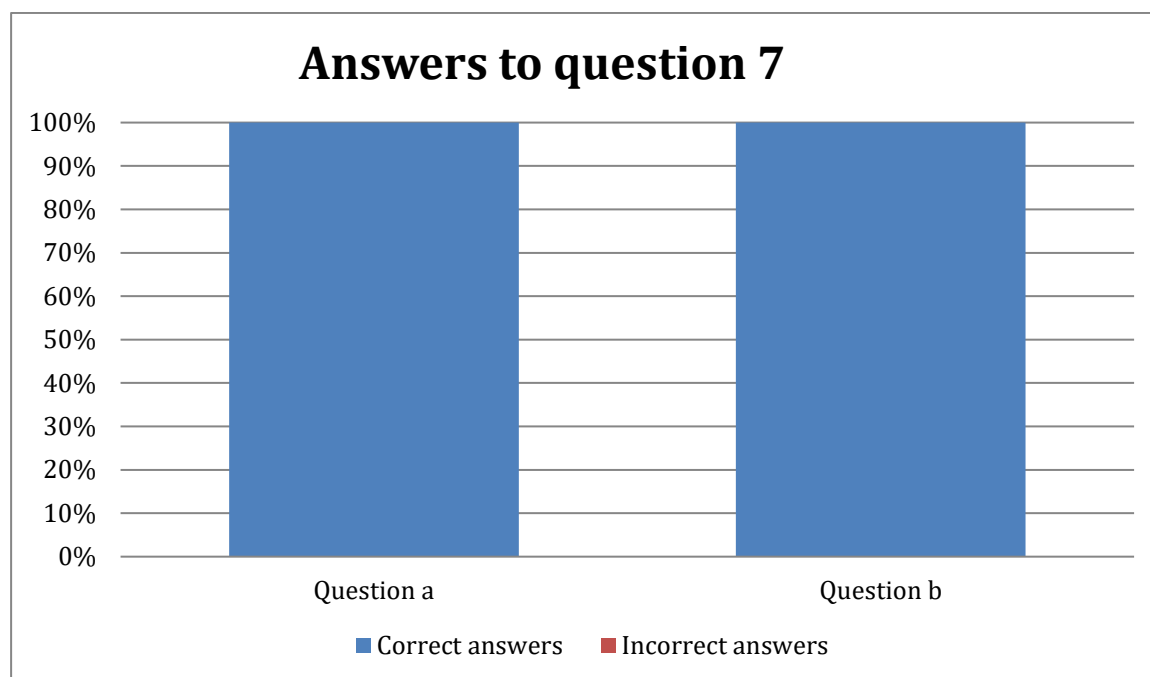


Figure 7 Correct and incorrect answers to question 7, pilot phase (%)

8. What should you do if you take more Promazine Syrup than you should?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 8A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 19 Results of question 8a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (3/3).

QUESTION 8B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 20 Results of question 8b, pilot phase (%)

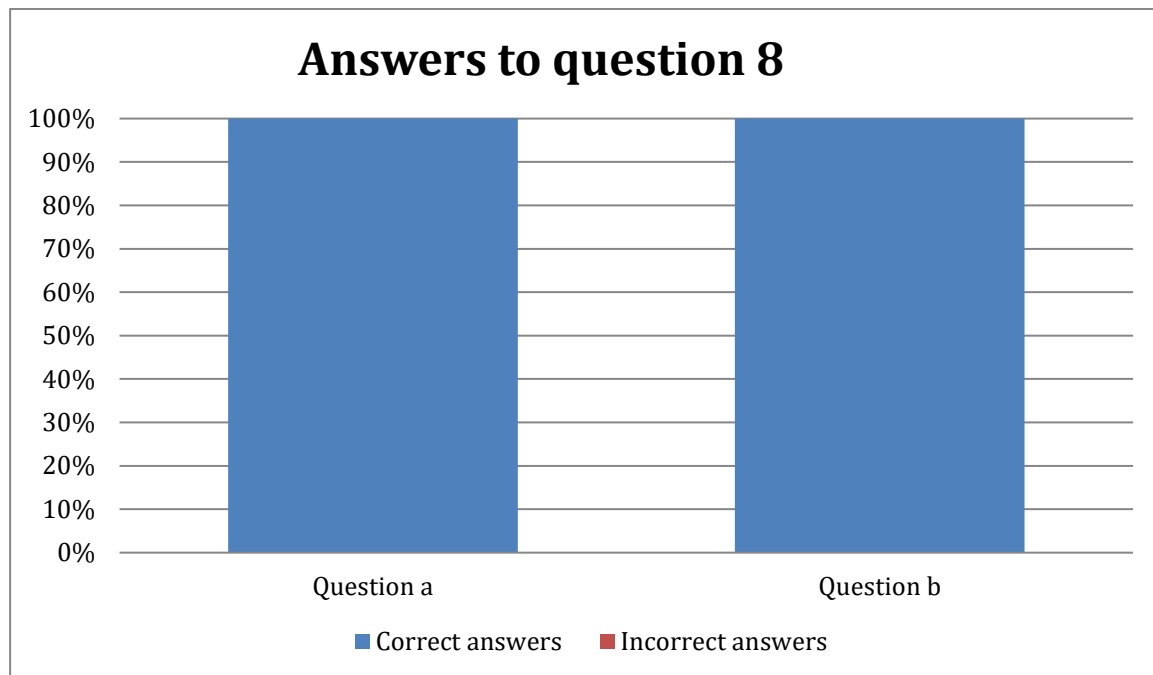


Figure 8. Correct and incorrect answers to question 8, pilot phase (%)

9. Can the children use Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 9A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 21 Results of question 9a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 9B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 22 Results of question 9b, pilot phase (%)

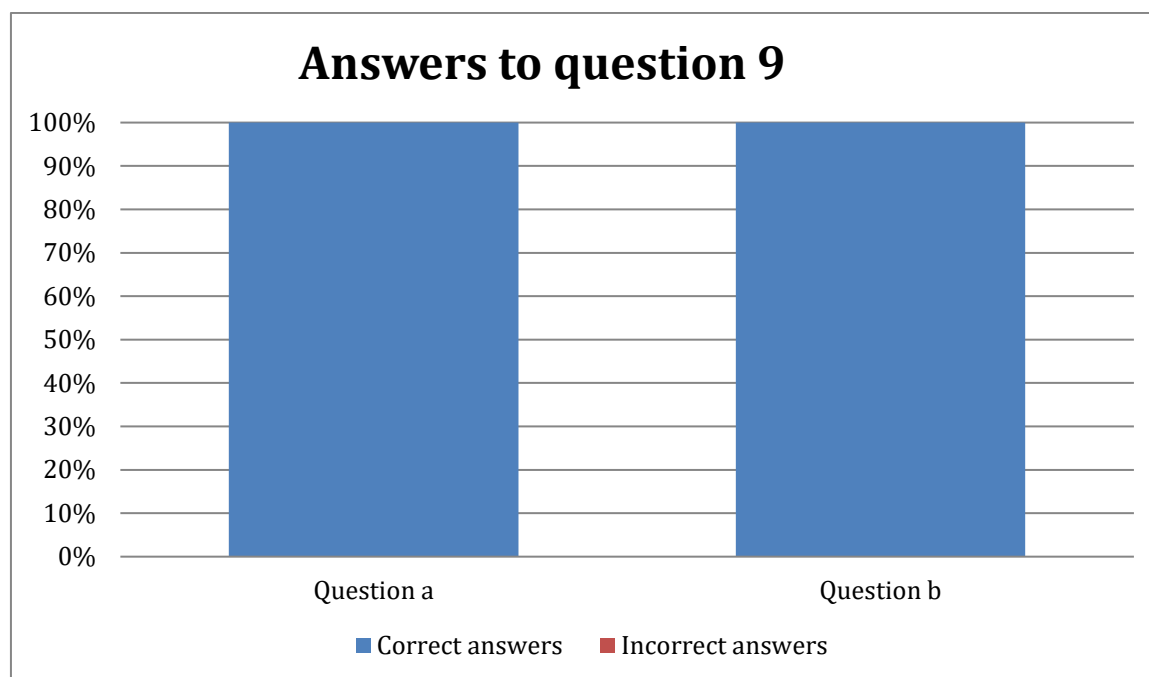


Figure 9 Correct and incorrect answers to question 9, pilot phase (%)

10. What should you do if you get any side effect after using Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 10A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 23 Results of question 10a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 10B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 24 Results of question 10b, pilot phase (%)

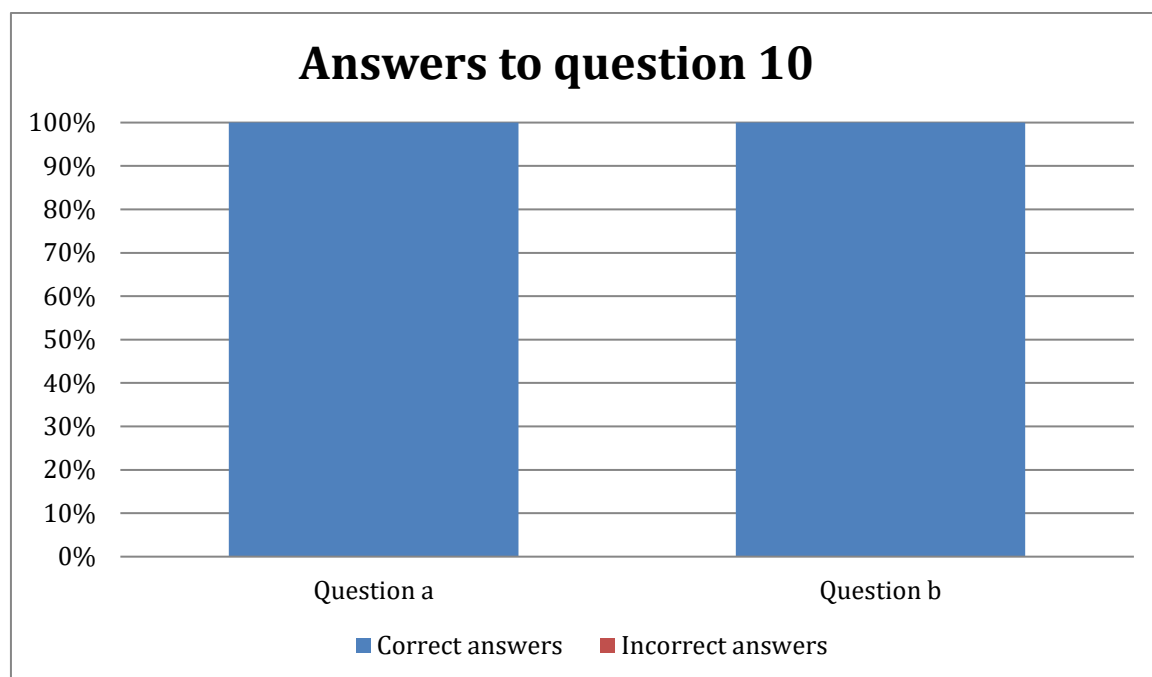


Figure 10. Correct and incorrect answers to question 10, pilot phase (%)

11. Does Promazine Syrup require special storage conditions?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 11A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Tabla 25. Resultados de la pregunta 11a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (3/3).

QUESTION 11B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 26 Results of question 11b, pilot phase (%)

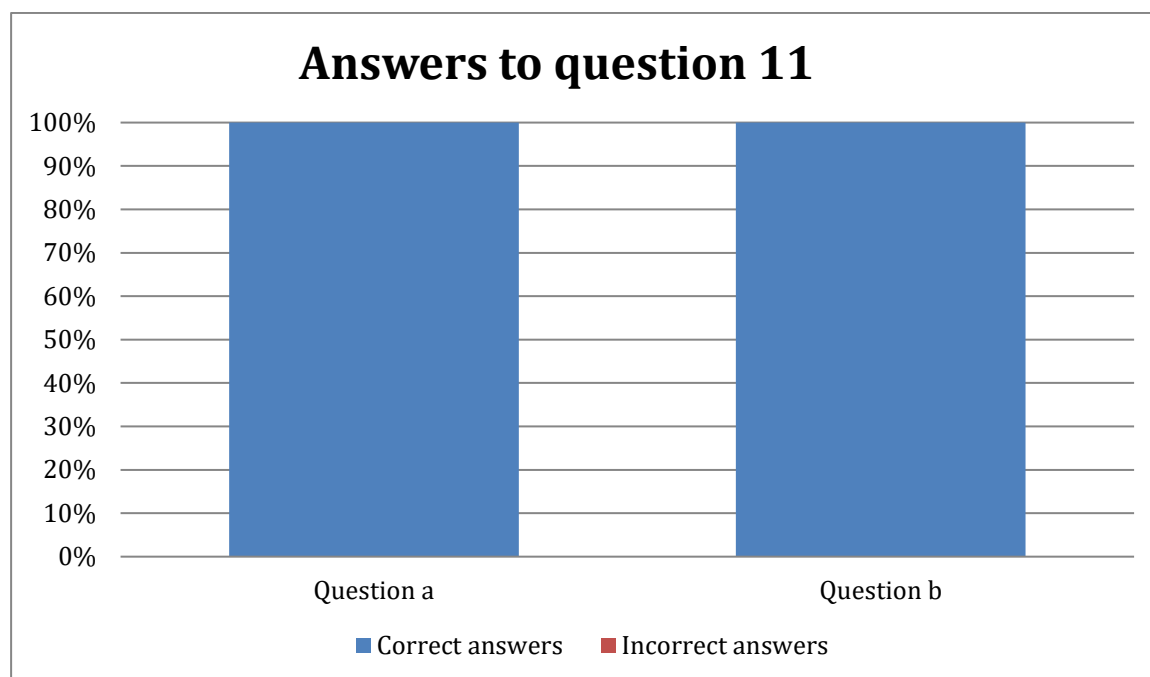


Figure 11 Correct and incorrect answers to question 11, pilot phase (%)

12. Can you use the medicinal product after the expiry date?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (3/3).

QUESTION 12A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 27 Results of question 12a, pilot phase (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (3/3).

QUESTION 12B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	3	100.0%	100.0%	100.0%
Total	3	100.0%		

Table 28 Results of question 12b, pilot phase (%)

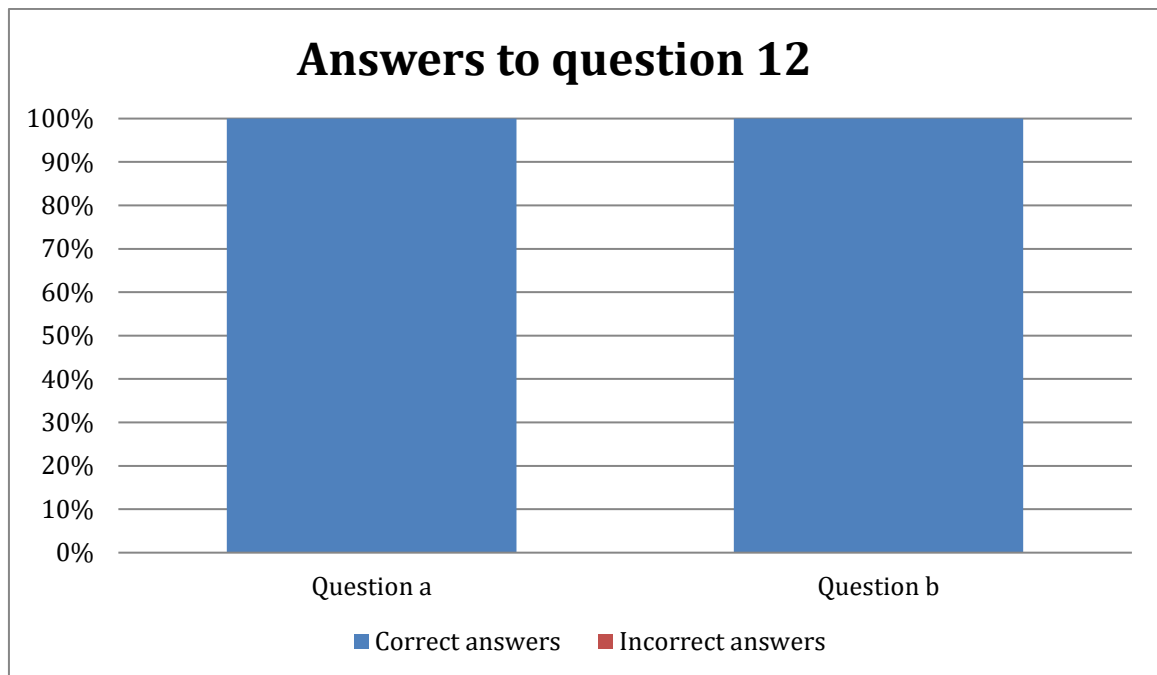


Figure 12 Correct and incorrect answers to question 12, pilot phase (%)

III. Interpretation of results of the pilot phase

For the 12 questions, the 3 volunteers interviewed in the pilot phase were able to correctly locate all the answers in the leaflet (3/3) as well as understand and explain them in their own words (3/3).

No problems in understanding the test were identified.

Based on these results, both the test and the leaflet were considered adequate, enabling initiation of the next phase of the study.

B. PHASE 1

I. Characteristics of the target population

Age and gender

For the 1st phase, 10 volunteers were recruited: 5 men and 5 women. Their ages were between 19 and 75 years old. The average age was 35.90, with a standard deviation of 18.47.

AGE

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	19	2	20.0%	20.0%	20.0%
	21	1	10.0%	10.0%	30.0%
	26	1	10.0%	10.0%	40.0%
	28	2	20.0%	20.0%	60.0%
	42	1	10.0%	10.0%	70.0%
	45	1	10.0%	10.0%	80.0%
	56	1	10.0%	10.0%	90.0%
	75	1	10.0%	10.0%	100.0%
Total		10	100.0%		

Table 29 Age of the participants in phase 1*

*("válido" means "valid", "frecuencia" means "frequency", "porcentaje" means "percentage", "porcentaje válido" means "valid percentage", and "porcentaje acumulado" means "cumulative percentage").

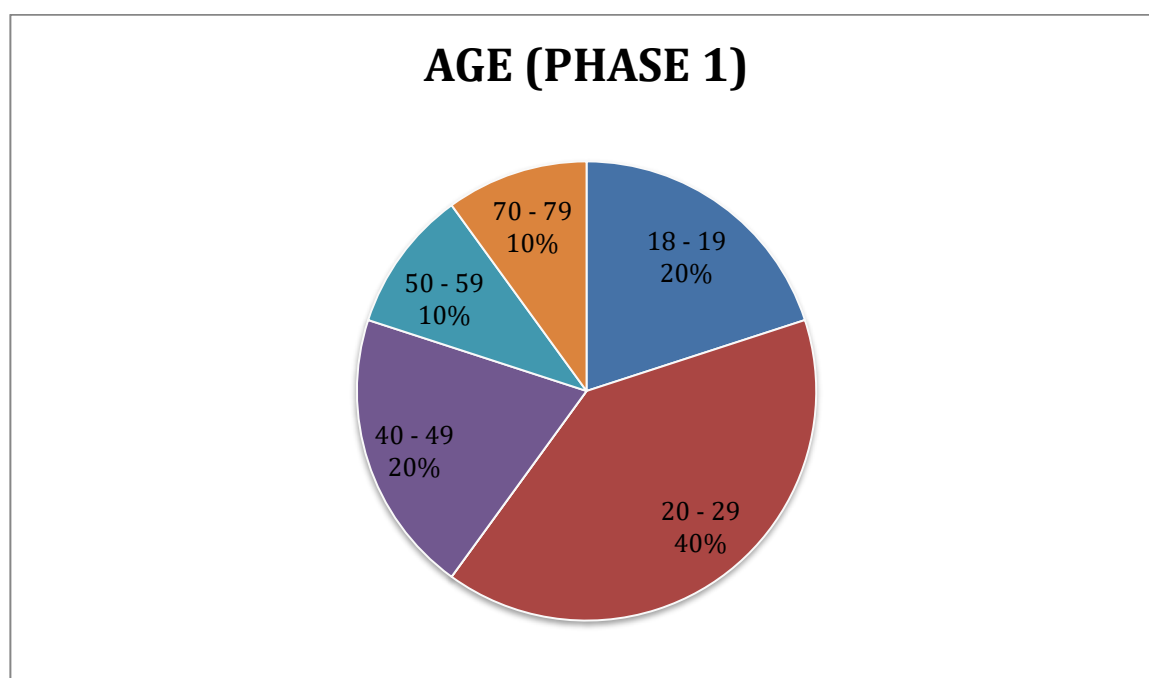


Figure 13 Age of the participants in phase 1

GENDER

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Man	5	50.0%	50.0%	50.0%
	Woman	5	50.0%	50.0%	100.0%
Total		10	100.0%		

Table 30 Gender of the participants in phase 1

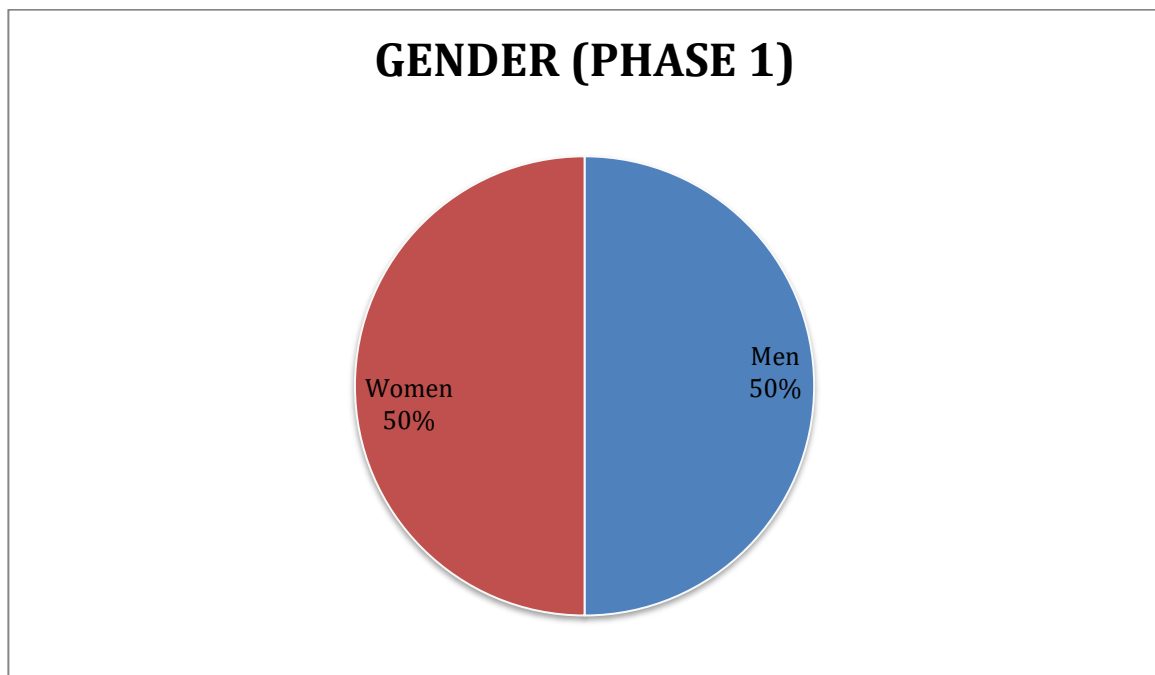


Figure 14 Gender of the participants in phase 1

Level of Education

The table below summarizes the level of education of the volunteers of the 1st phase. There were 3 participants with a High school level or equivalents, 1 participant with Vocational training or equivalents, 1 participant with Undergraduate degree, 2 participants with Bachelor degree and other 3 participants with Postgraduate degree.

LEVEL OF EDUCATION

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	High school level or equivalents	3	30.0%	30.0%	30.0%
	Vocational training or equivalents	1	10.0%	10.0%	40.0%
	Undergraduate degree	1	10.0%	10.0%	50.0%
	Bachelor degree	2	20.0%	20.0%	70.0%
	Postgraduate degree	3	30.0%	30.0%	100.0%
Total		10	100.0%		

Table 31 Level of Education of the participants in phase 1

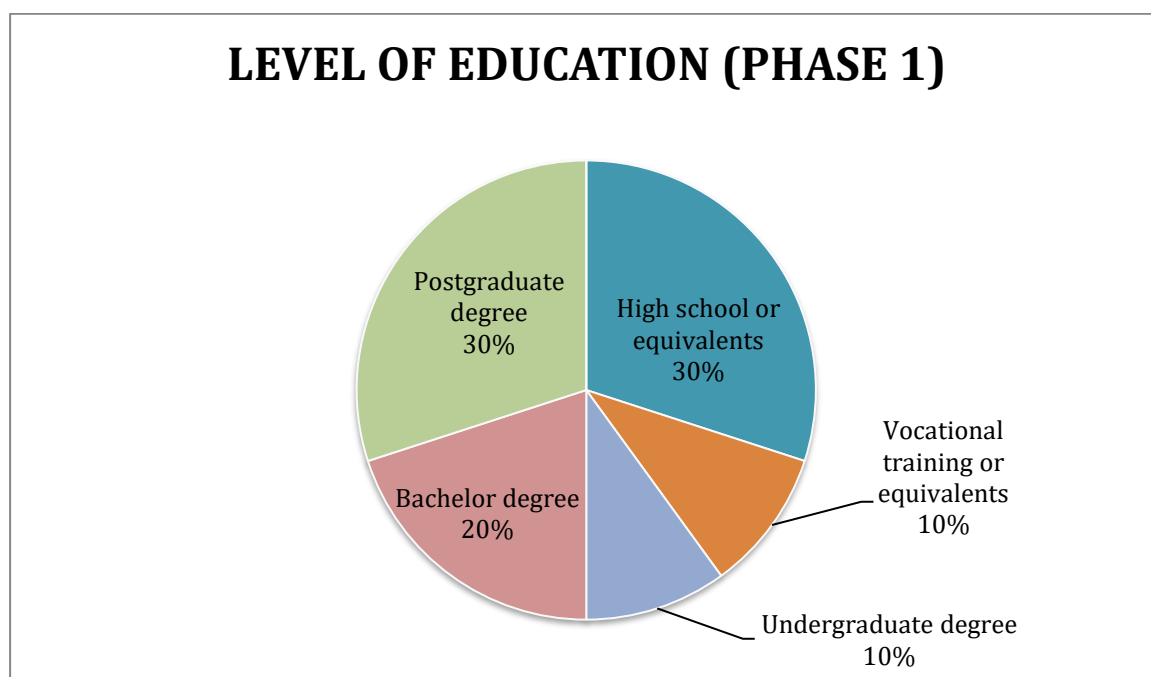


Figure 15 Level of education of the participants in phase 1

Visual disorders

It is also analysed if the participants had visual disorders, such as myopia, astigmatism, hyperopia, presbyopia, etc. Information on whether they wear glasses or contact lenses to overcome the impairments is also available.

Three volunteers in the 1st phase had visual disorders, specifically 2 with myopia and 1 with myopia and astigmatism. All of them wear glasses or contact lenses to solve the problems.

VISUAL DISORDERS

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	NO	7	70.0%	70.0%	70.0%
	YES	3	30.0%	30.0%	100.0%
Total		10	100.0%		

Table 32 Visual disorders of the participants in phase 1

II. Results of the readability test

Below are the percentages of hits and mistakes for the 12 questions of the readability test. Each question consists of 2 sections: section "a" determines the ability to locate the answer in the leaflet, and section "b" evaluates the ability to understand the answer given in the leaflet and express it in their own words.

1. What Promazine Syrup used for?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 1A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	10	100.0%	100.0%	100.0%
Total		10	100.0%		

Table 33 Results of question 1a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (10/10).

QUESTION 1B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	10	100.0%	100.0%	100.0%
Total		10	100.0%		

Table 34 Results of question 1b, phase 1 (%)

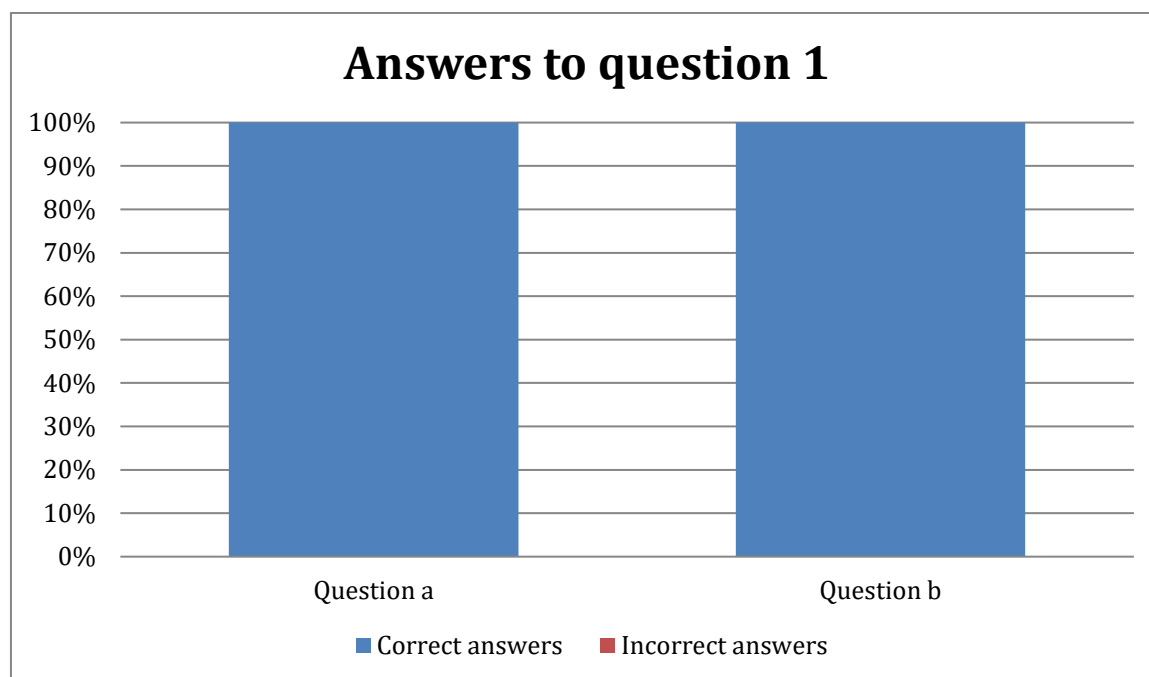


Figure 16 Correct and incorrect answers to question 1, phase 1 (%)

2. Can you take Promazine Syrup if you are allergic to promazine?
 a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 2A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	10	100.0%	100.0%	100.0%
Total		10	100.0%		

Table 35 Results of question 2a, phase 1 (%)

- b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (10/10).

QUESTION 2B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	10	100.0%	100.0%	100.0%
Total		10	100.0%		

Table 36 Results of question 2b, phase 1 (%)

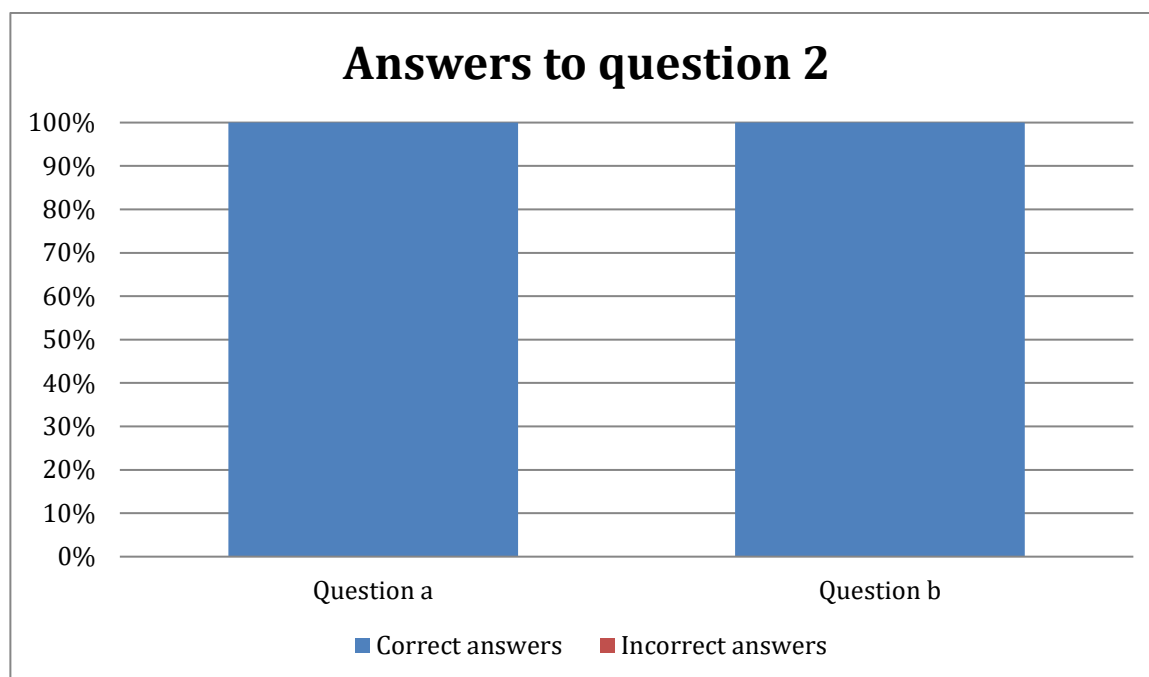


Figure 17 Correct and incorrect answers to question 2, phase 1 (%)

3. Can you take Promazine Syrup if you have bone marrow depression?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 3A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 37 Results of question 3a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 3B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 38 Results of question 3b, phase 1 (%)

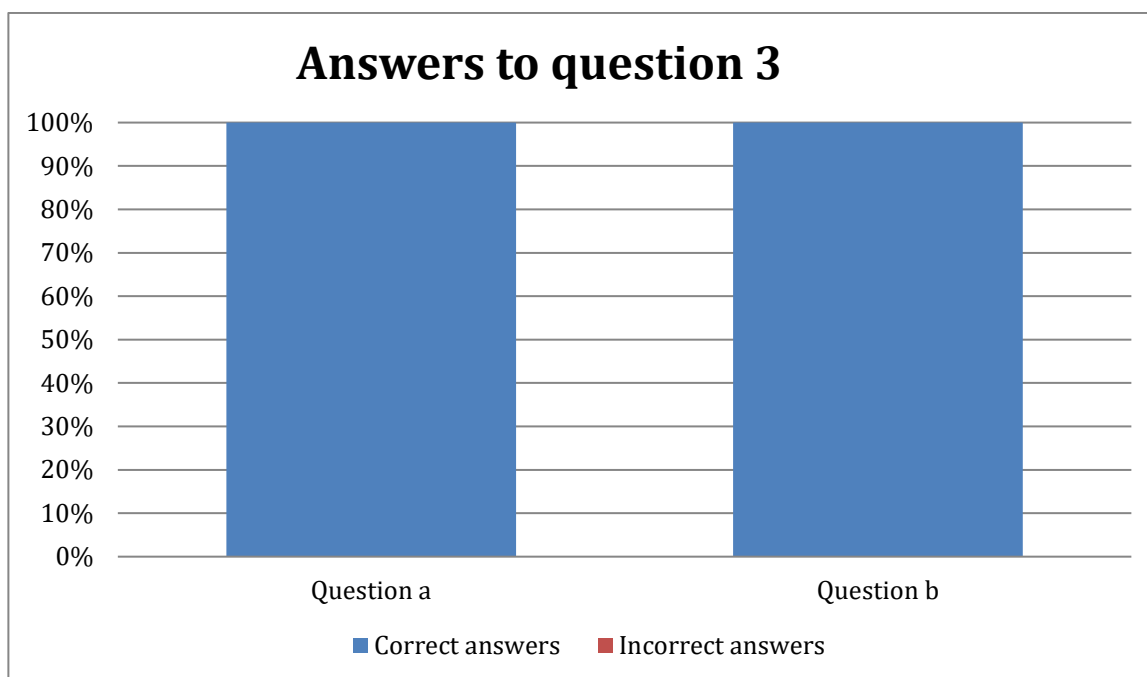


Figure 18 Correct and incorrect answers to question 3, phase 1 (%)

4. Can a patient breast-feed take Promazine Syrup without ask a doctor?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 4A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 39 Results of question 4a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (10/10).

QUESTION 4B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 40 Results of question 4b, phase 1 (%)

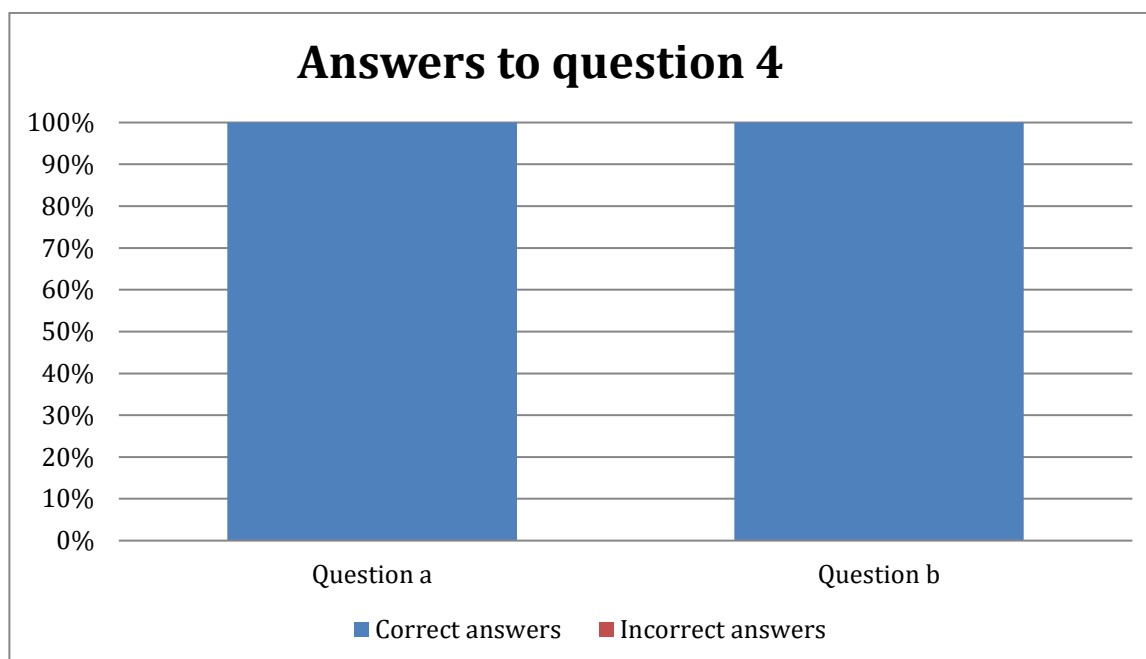


Figure 19 Correct and incorrect answers to question 4, phase 1 (%)

5. What is the recommended dose for Promazine Syrup in adults?
 a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 5A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	10	100.0%	100.0%	100.0%
Total		10	100.0%		

Table 41 Results of question 5a, phase 1 (%)

- b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 5B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	10	100.0%	100.0%	100.0%
Total		10	100.0%		

Table 42 Results of question 5b, phase 1 (%)

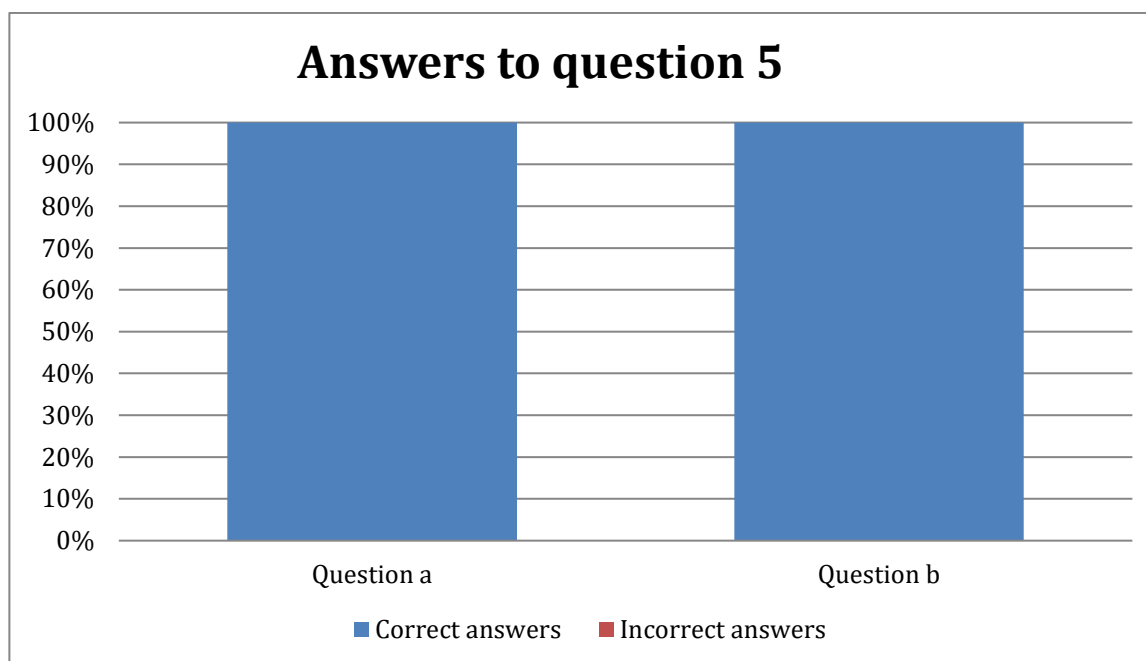


Figure 20 Correct and incorrect answers to question 5, phase 1 (%)

6. Can you drive if you are under Promazine Syrup treatment?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 6A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 43 Results of question 6a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (10/10).

QUESTION 6B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 44 Results of question 6b, phase 1 (%)

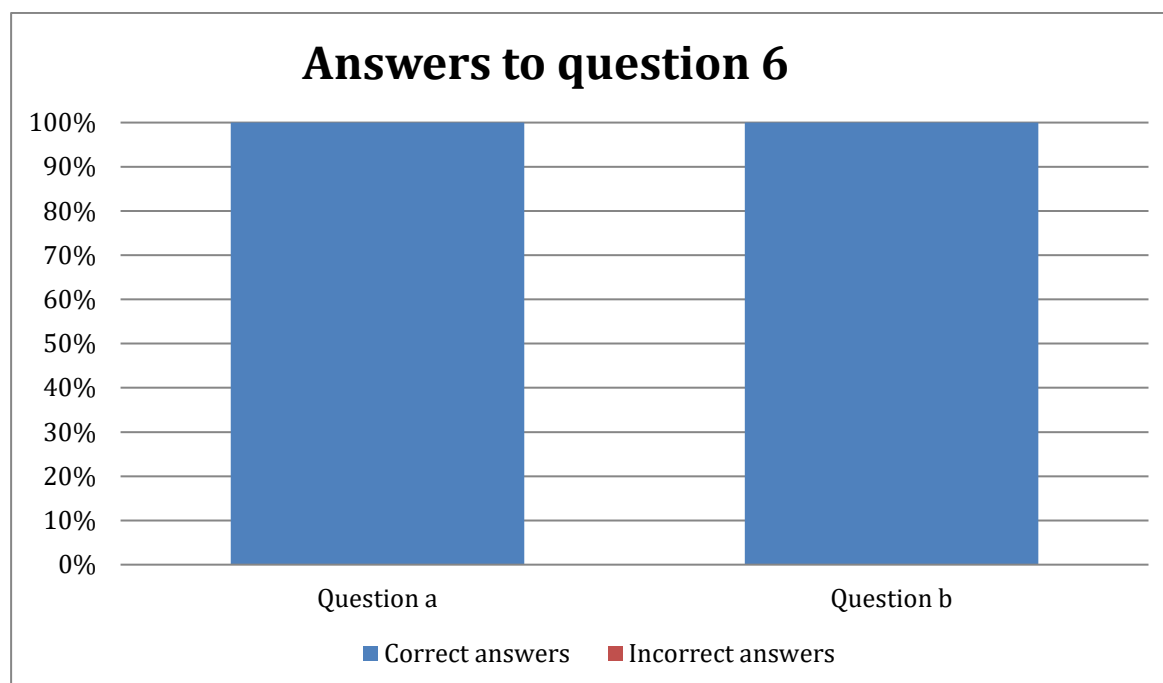


Figure 21 Correct and incorrect answers to question 6, phase 1 (%)

7. Can you take alcohol if you take Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 7A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 45 Results of question 7a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 7B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 46 Results of question 7b, phase 1 (%)

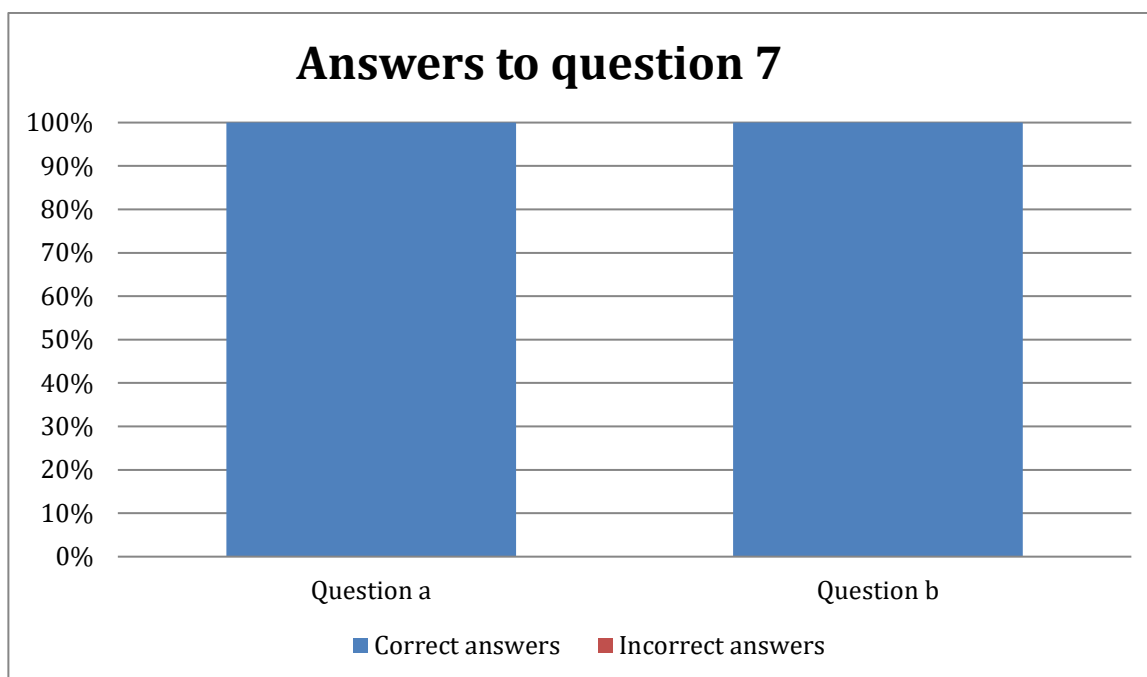


Figure 22 Correct and incorrect answers to question 7, phase 1 (%)

8. What should you do if you take more Promazine Syrup than you should?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 8A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 47 Results of question 8a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (10/10).

QUESTION 8B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 48 Results of question 8b, phase 1 (%)

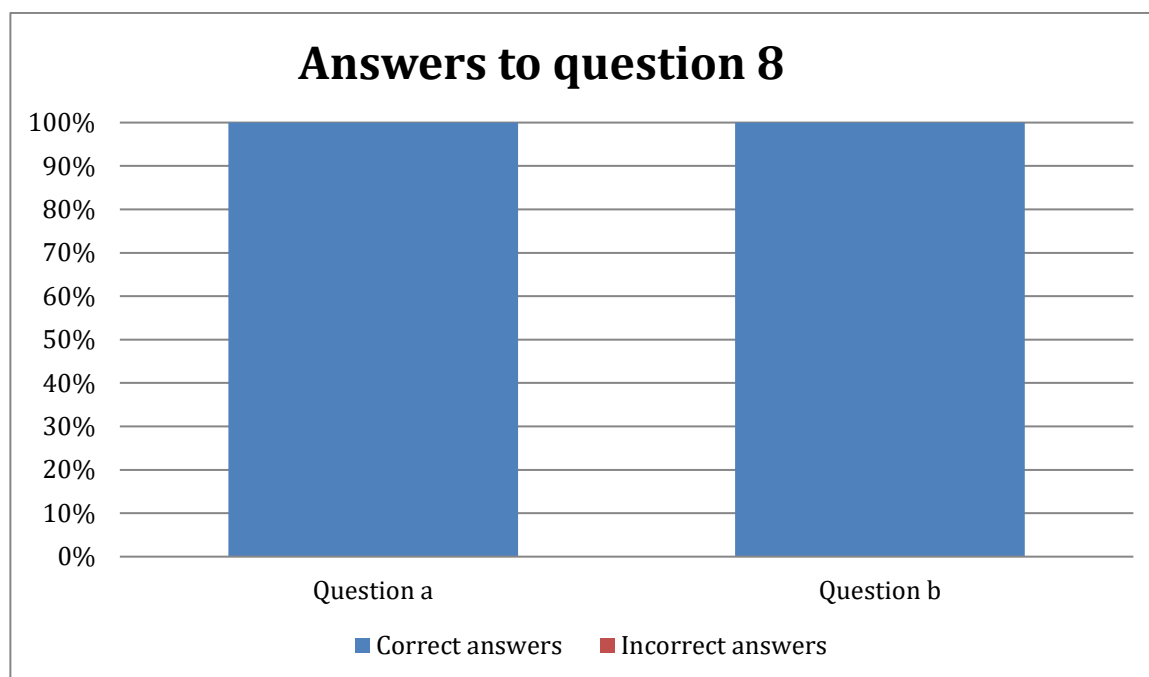


Figure 23 Correct and incorrect answers to question 8, phase 1 (%)

9. Can the children use Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 9A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 49 Results of question 9a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 9B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 50 Results of question 9b, phase 1 (%)

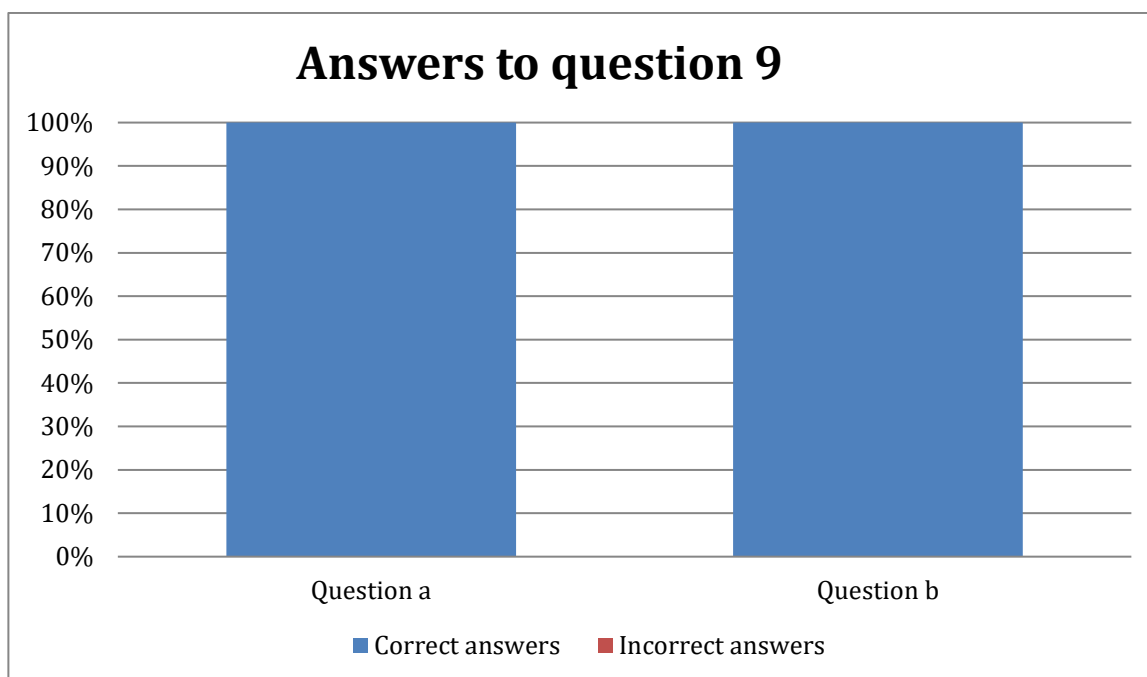


Figure 24 Correct and incorrect answers to question 9, phase 1 (%)

10. What should you do if you get any side effect after using Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 10A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 51 Results of question 10a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (10/10).

QUESTION 10B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 52 Results of question 10b, phase 1 (%)

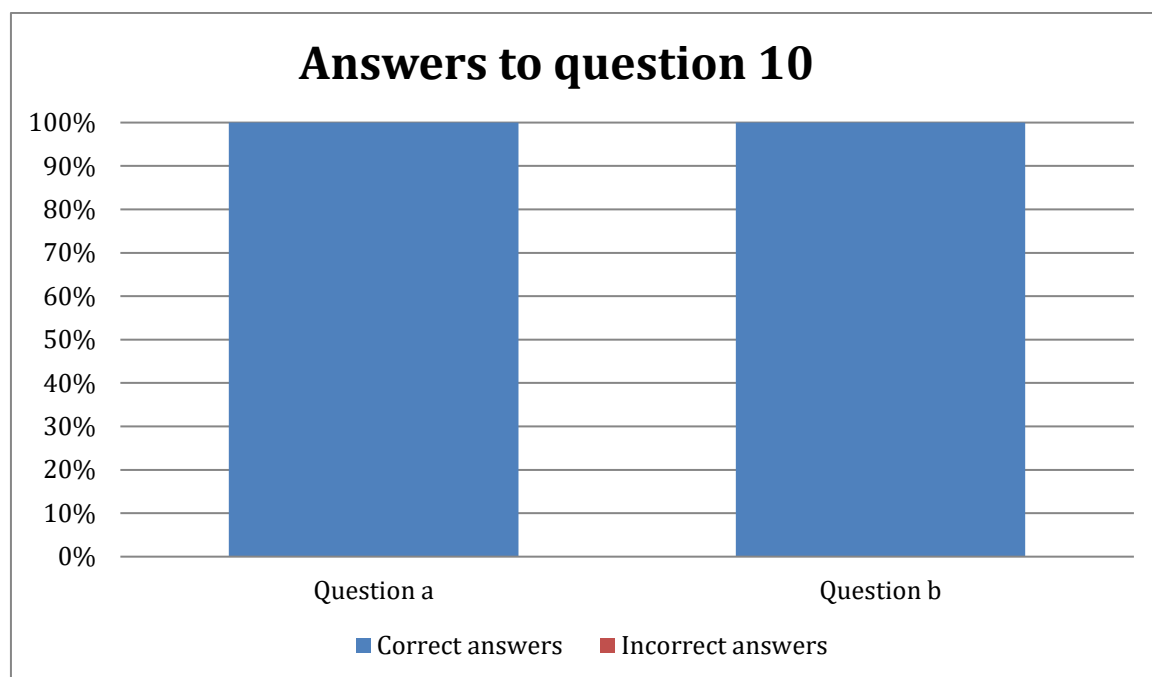


Figure 25 Correct and incorrect answers to question 10, phase 1 (%)

11. Does Promazine Syrup require special storage conditions?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 11A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 53 Results of question 11a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (10/10).

QUESTION 11B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 54 Results of question 11b, phase 1 (%)

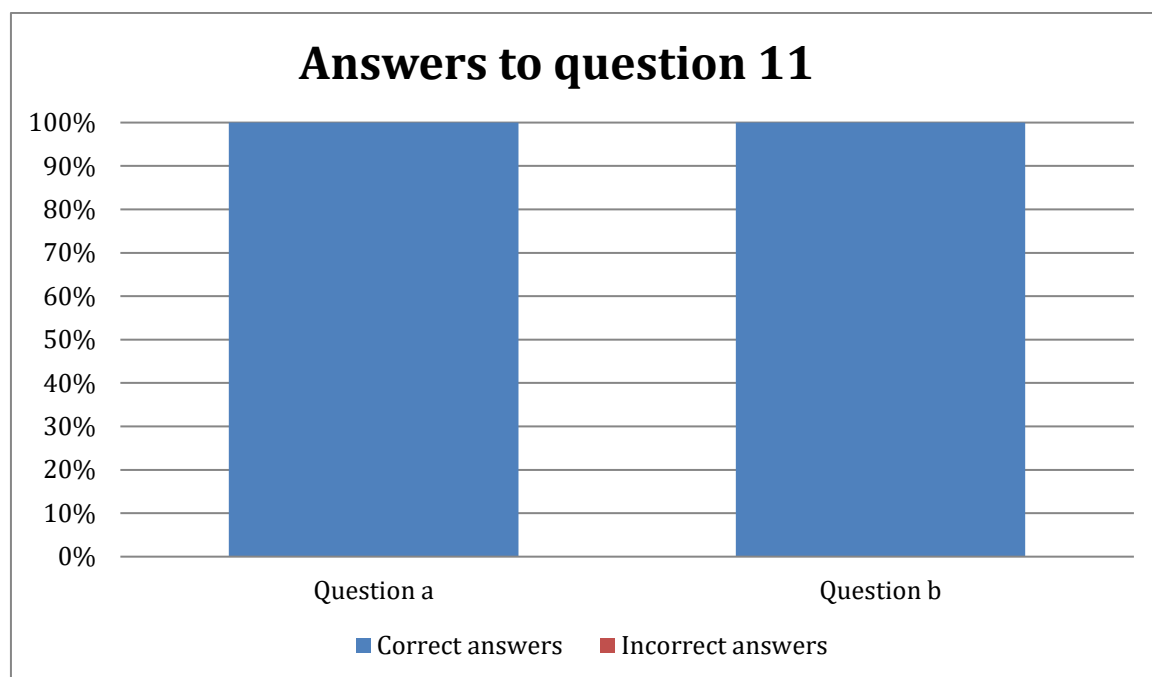


Figure 26 Correct and incorrect answers to question 11, phase 1 (%)

12. Can you use the medicinal product after the expiry date?

a) Where can the answer to this question be found in the leaflet?

100% of the participants were able to correctly locate the answer in the leaflet (10/10).

QUESTION 12A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 55 Results of question 12a, phase 1 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 12B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 56 Results of question 12b, phase 1 (%)

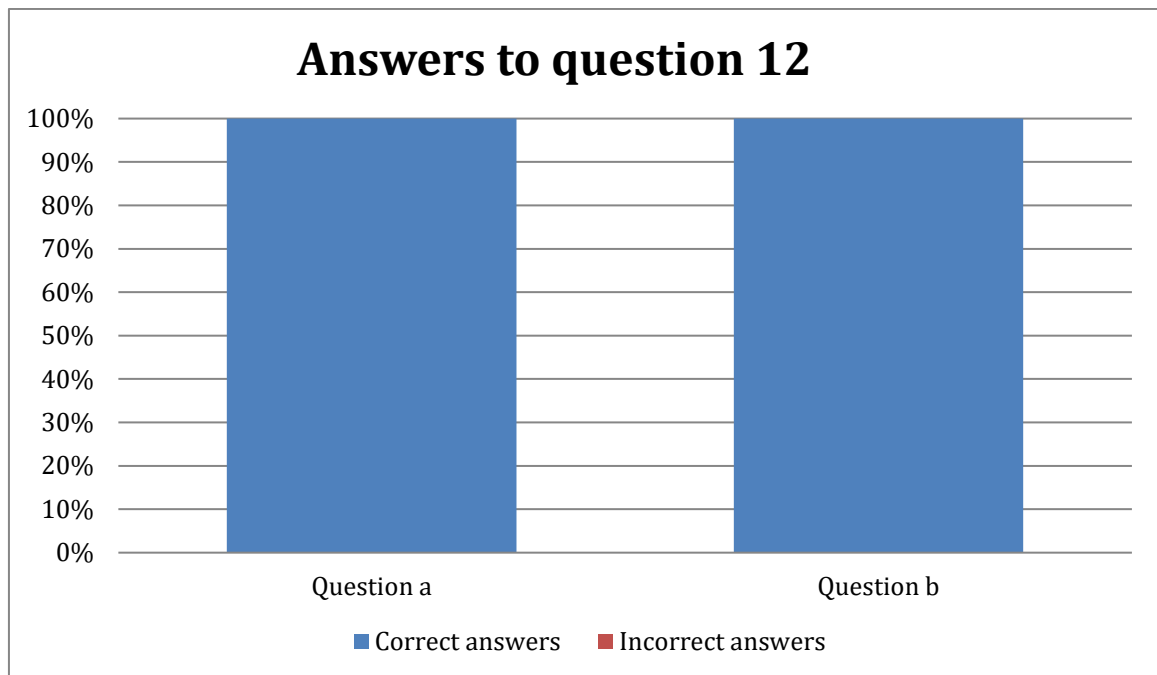


Figure 27 Correct and incorrect answers to question 12, phase 1 (%)

III. Interpretation of results for phase 1

For all questions, all the participants (10/10) were able to find the information in the leaflet and answer the question correctly. Therefore, **100% of the participants in phase 1 (10/10) were able to locate and understand properly the answers to the questions.**

Based on these results, both the test and the leaflet were considered adequate without requiring changes, enabling initiation of the next and last phase of the study.

C. PHASE 2

I. Characteristics of the target population

Age and gender

For the 2nd phase, 10 volunteers were recruited: 5 men and 5 women. Their ages were between 19 and 75 years old. The average age was 39.90, with a standard deviation of 18.13.

AGE

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	19	1	10.0%	10.0%	10.0%
	22	1	10.0%	10.0%	20.0%
	26	1	10.0%	10.0%	30.0%
	27	1	10.0%	10.0%	40.0%
	28	1	10.0%	10.0%	50.0%
	47	1	10.0%	10.0%	60.0%
	51	2	20.0%	20.0%	80.0%
	53	1	10.0%	10.0%	90.0%
	75	1	10.0%	10.0%	100.0%
Total		10	100.0%		

Table 57 Age of the participants in phase 2*

*("válido" means "valid", "frecuencia" means "frequency", "porcentaje" means "percentage", "porcentaje válido" means "valid percentage", and "porcentaje acumulado" means "cumulative percentage").

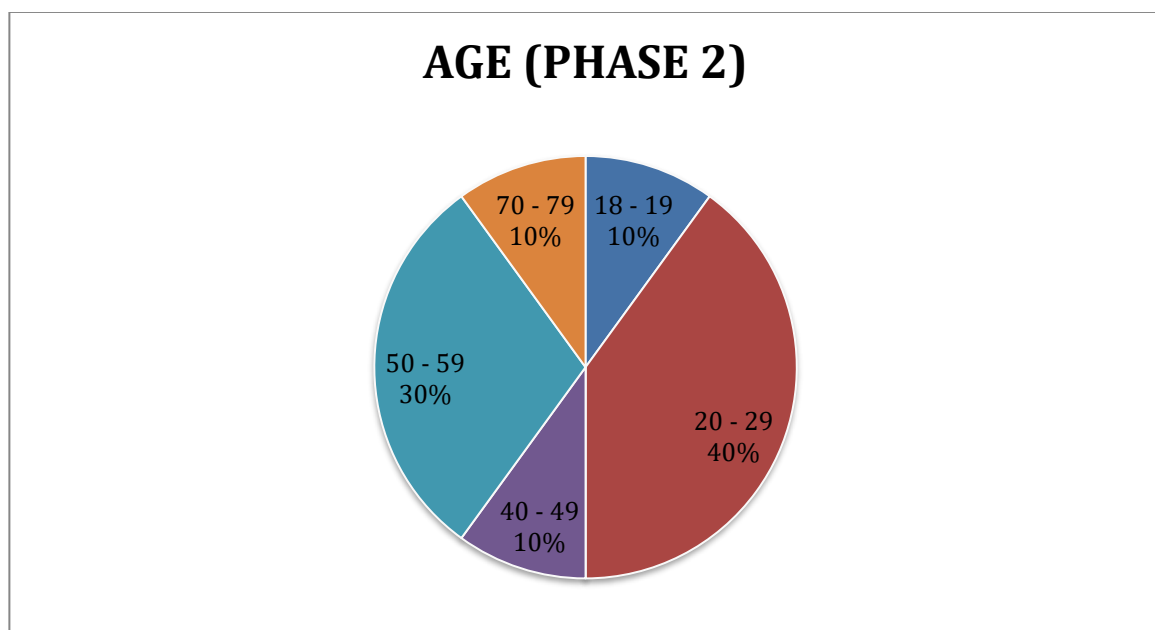


Figure 28 Age of the participants in phase 2

GENDER

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Man	5	50.0%	50.0%	50.0%
	Woman	5	50.0%	50.0%	100.0%
Total		10	100.0%		

Table 58 Gender of the participants in phase 2

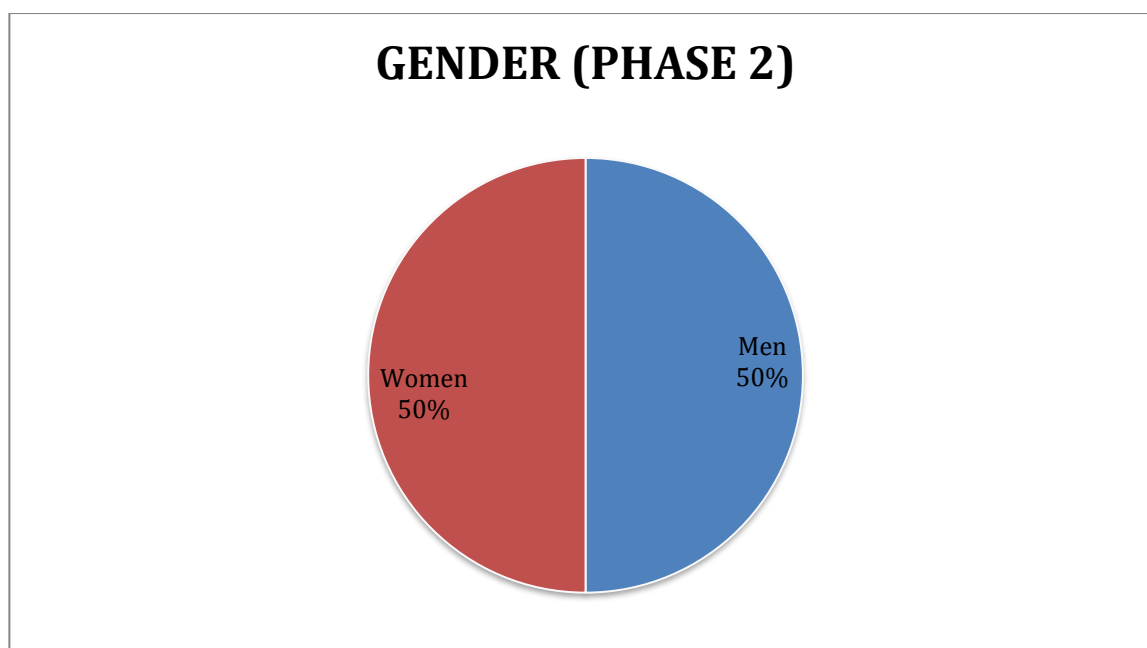


Figure 29 Gender of the participants in phase 2

Level of Education

The table below summarizes the level of education of the volunteers of the 2nd phase. There were 3 participants with High school level or equivalents, 2 participants with Vocational training or equivalents, 3 participants with a Bachelor degree and other 2 with a Postgraduate degree.

LEVEL OF EDUCATION

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	High school level or equivalents	3	30.0%	30.0%	30.0%
	Vocational training or equivalents	2	20.0%	20.0%	50.0%
	Bachelor degree	3	30.0%	30.0%	80.0%
	Postgraduate degree	2	20.0%	20.0%	100.0%
Total		10	100.0%		

Table 59 Level of Education of the participants in phase 2

LEVEL OF EDUCATION (PHASE 2)

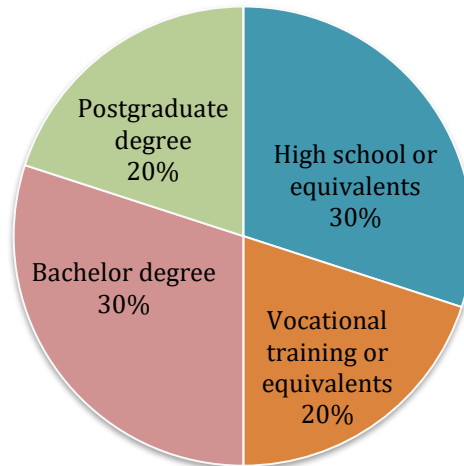


Figure 30 Level of education of the participants in phase 2

Visual disorders

It is also analysed if the participants had visual disorders, such as myopia, astigmatism, hyperopia, presbyopia, etc. Information on whether they wear glasses or contact lenses to overcome the impairments is also available.

Four volunteers in the 2nd phase had visual disorders, specifically myopia (2 participants), myopia and astigmatism (1) and presbyopia (1 participant). All of them wear glasses or contact lenses to solve the problems.

VISUAL DISORDERS

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido NO	6	60.0%	60.0%	60.0%
YES	4	40.0%	40.0%	100.0%
Total	10	100.0%		

Table 60 Visual disorders of the participants in phase 2

II. Results of the readability test

Below are the percentages of hits and mistakes for the 12 questions of the readability test. Each question consists of 2 sections: section “a” determines the ability to locate the answer in the leaflet, and section “b” evaluates the ability to understand the answer given in the leaflet and express it in their own words.

1. What Promazine Syrup used for?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 1A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 61 Results of question 1a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (10/10).

QUESTION 1B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 62 Results of question 1b, phase 2 (%)

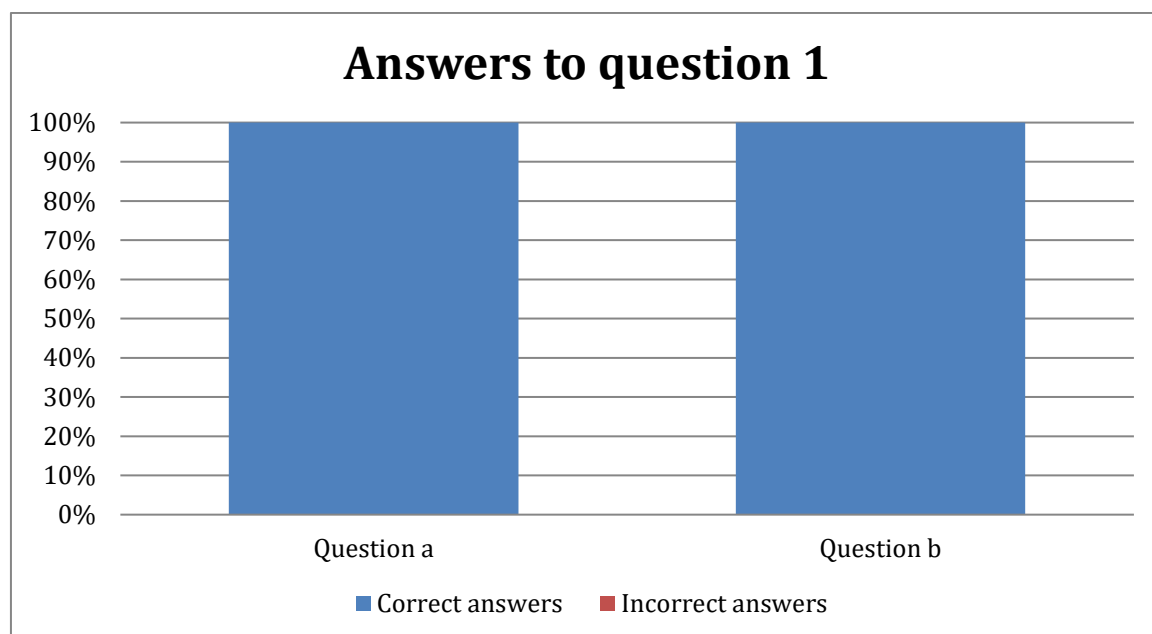


Figure 31 Correct and incorrect answers to question 1, phase 2 (%)

2. Can you take Promazine Syrup if you are allergic to promazine?
 a) Where can the answer to this question be found in the leaflet?

100% of the participants could correctly find the answer in the leaflet (10/10).

QUESTION 2A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 63 Results of question 2a, phase 2 (%)

- b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (10/10).

QUESTION 2B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correcto	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 64 Results of question 2b, phase 2 (%)

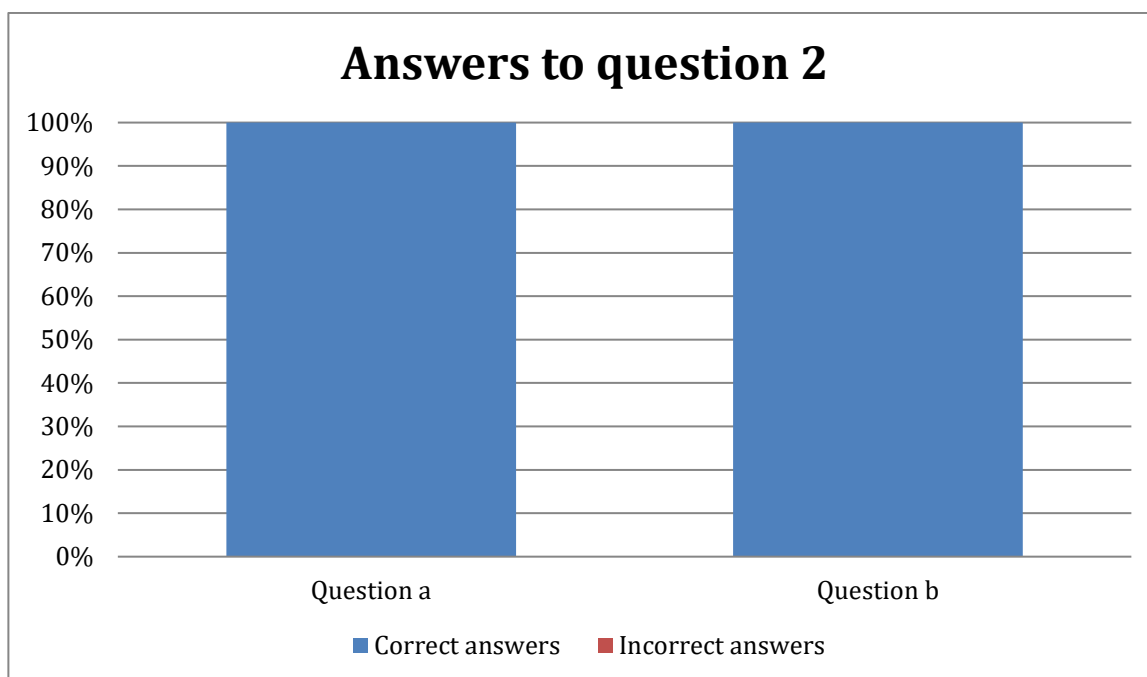


Figure 32 Correct and incorrect answers to question 2, phase 2 (%)

3. Can you take Promazine Syrup if you have bone marrow depression?

100% of the participants were able to correctly locate the answer in the leaflet (10/10).

QUESTION 3A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 65 Results of question 3a, phase 2 (%)

a) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 3B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 66 Results of question 3b, phase 2 (%)

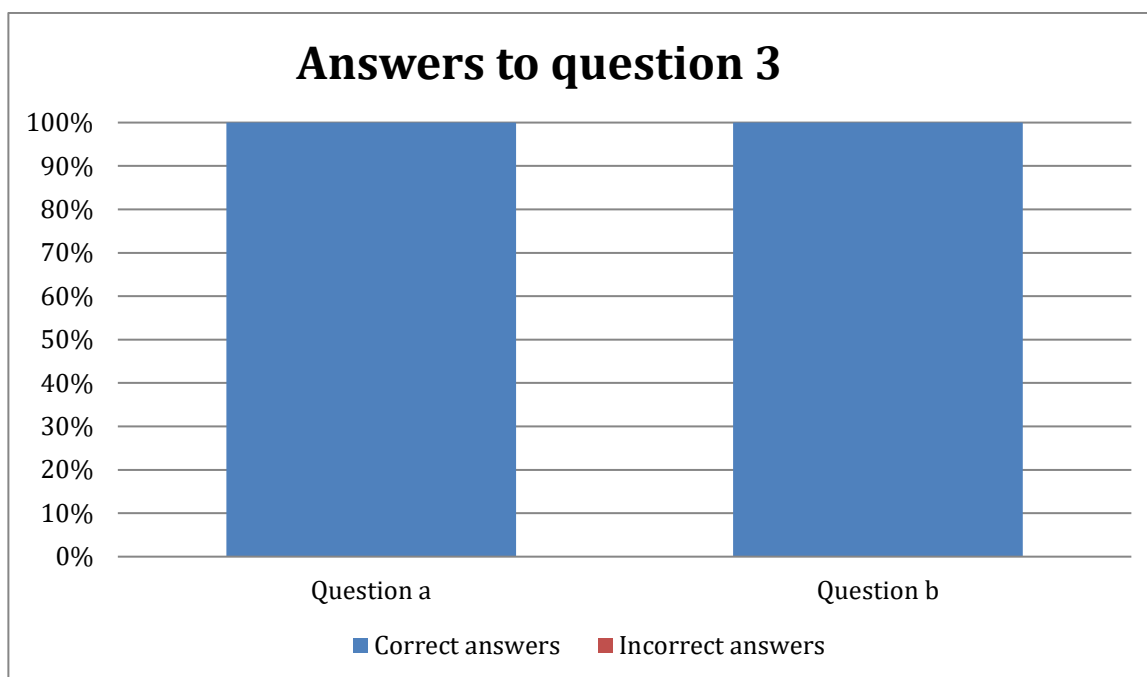


Figure 33 Correct and incorrect answers to question 3, phase 2 (%)

4. Can a patient breast-feed take Promazine Syrup without ask a doctor?

a) Where can the answer to this question be found in the leaflet?

100% of the participants found the answer in the leaflet (10/10).

QUESTION 4A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 67 Results of question 4a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (10/10).

QUESTION 4B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 68 Results of question 4b, phase 2 (%)

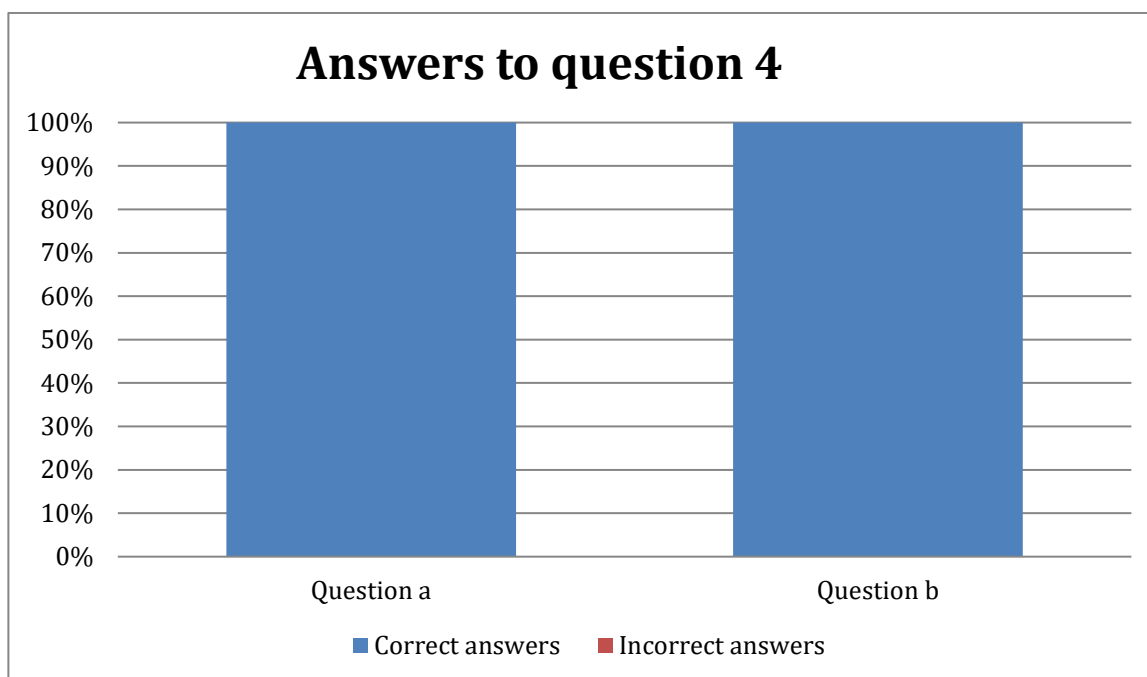


Figure 34 Correct and incorrect answers to question 4, phase 2 (%)

5. What is the recommended dose for Promazine Syrup in adults?
 a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 5A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 69 Results of question 5a, phase 2 (%)

- b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (10/10).

QUESTION 5B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 70 Results of question 5b, phase 2 (%)

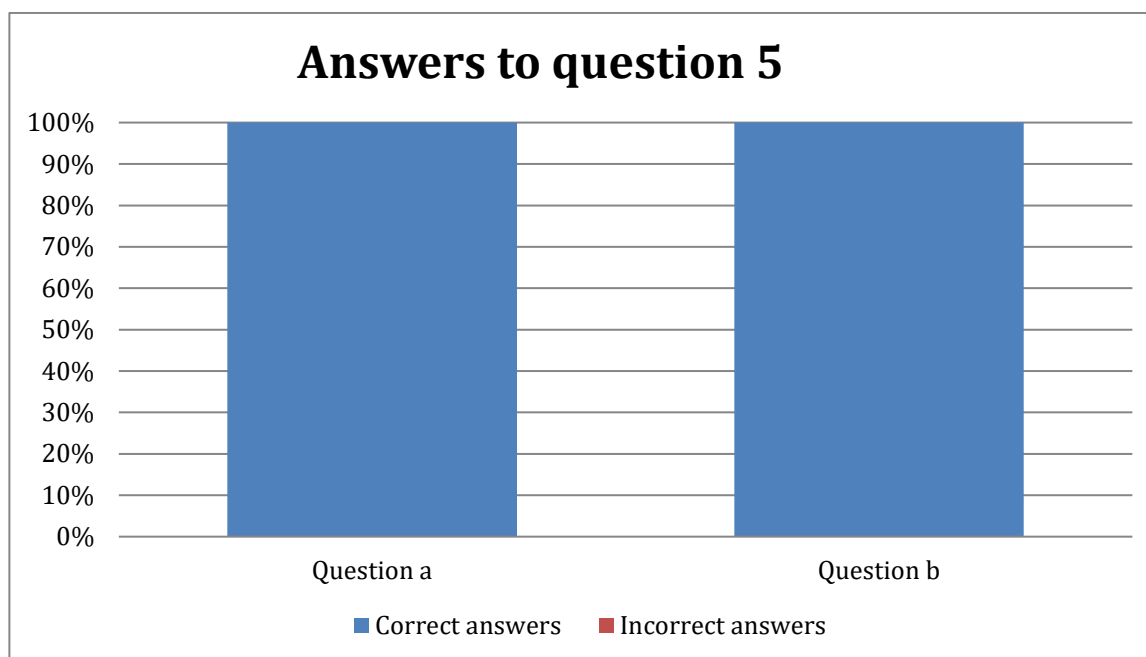


Figure 35 Correct and incorrect answers to question 5, phase 2 (%)

6. Can you drive if you are under Promazine Syrup treatment?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 6A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 71 Results of question 6a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (10/10).

QUESTION 6B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 72 Results of question 6b, phase 2 (%)

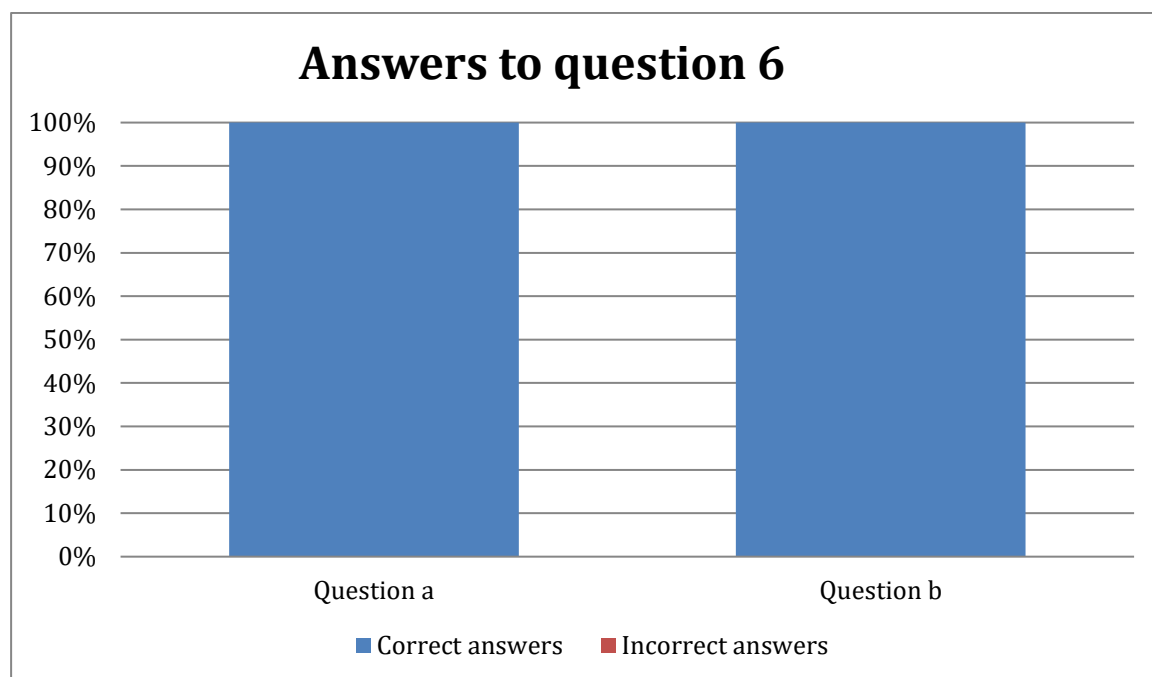


Figure 36 Correct and incorrect answers to question 6, phase 2 (%)

7. Can you take alcohol if you take Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants could find the answer in the leaflet (10/10).

QUESTION 7A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 73 Results of question 7a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (10/10).

QUESTION 7B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 74 Results of question 7b, phase 2 (%)

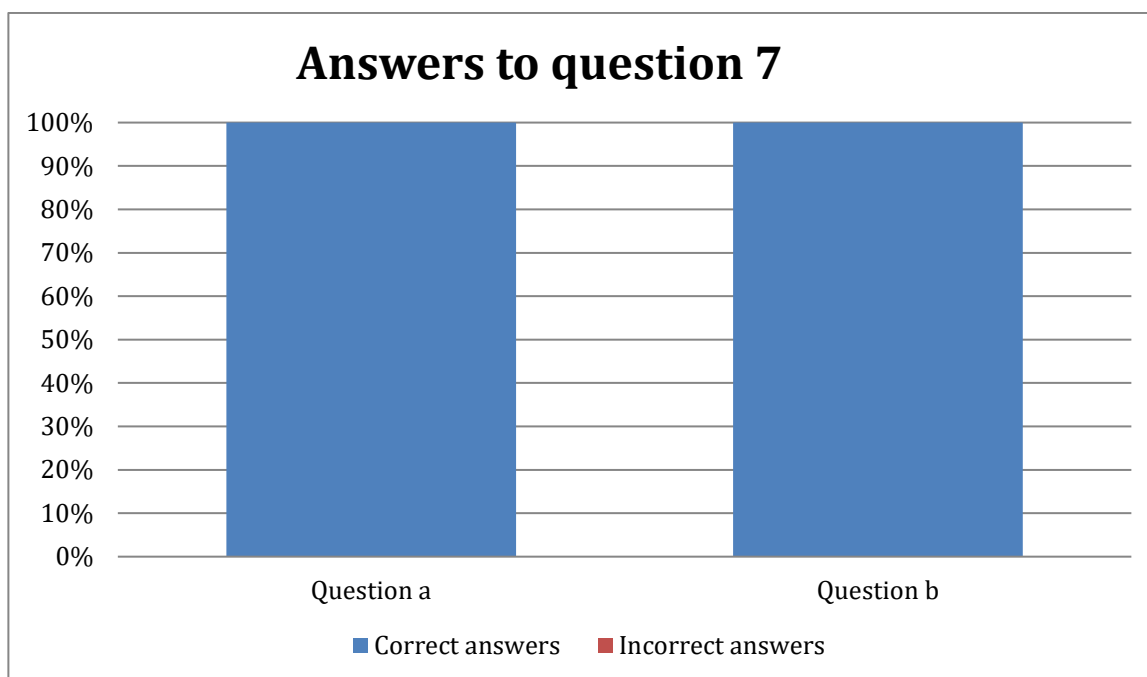


Figure 37 Correct and incorrect answers to question 7, phase 2 (%)

8. What should you do if you take more Promazine Syrup than you should?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly found the answer in the leaflet (10/10).

QUESTION 8A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 75 Results of question 8a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (10/10).

QUESTION 8B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 76 Results of question 8b, phase 2 (%)

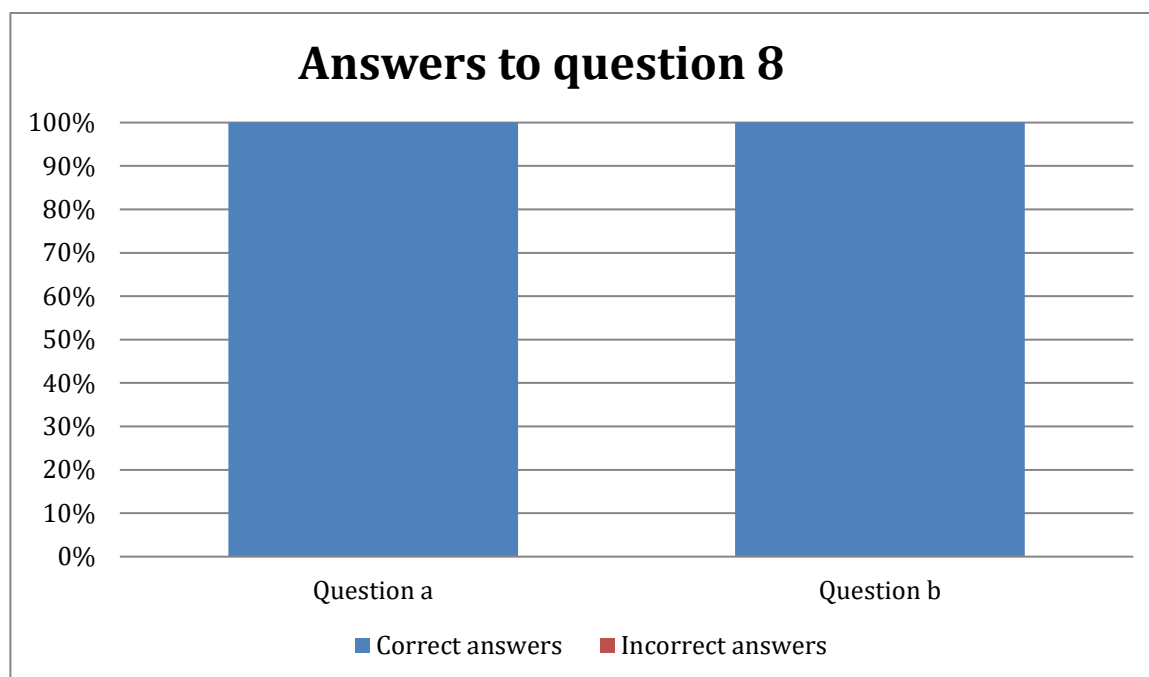


Figure 38 Correct and incorrect answers to question 8, phase 2 (%)

9. Can the children use Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 9A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 77 Results of question 9a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (10/10).

QUESTION 9B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 78 Results of question 9b, phase 2 (%)

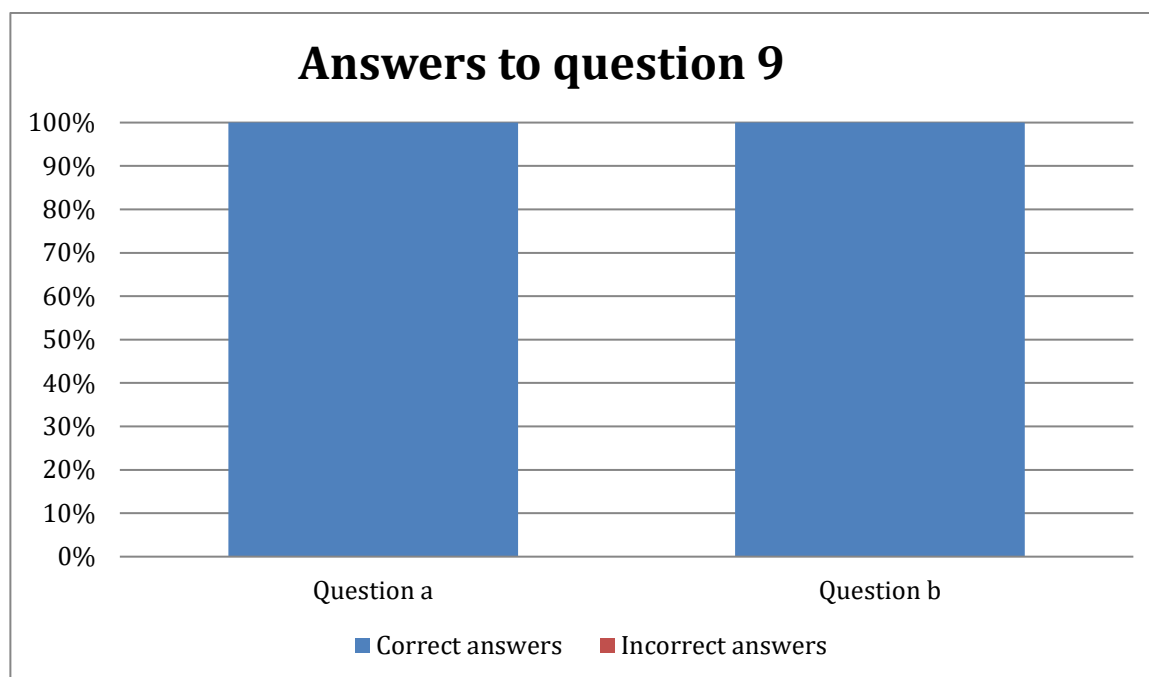


Figure 39 Correct and incorrect answers to question 9, phase 2 (%)

10. What should you do if you get any side effect after using Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 10A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 79 Results of question 10a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and could answer in their own words (10/10).

QUESTION10B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 80 Results of question 10b, phase 2 (%)

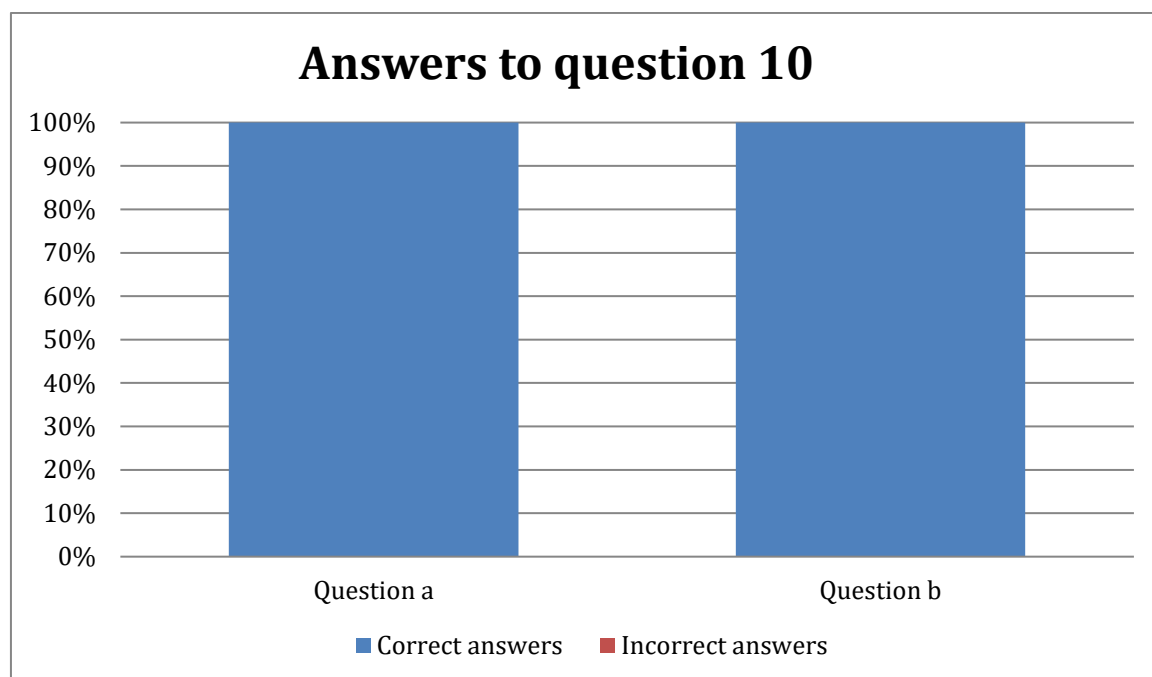


Figure 40 Correct and incorrect answers to question 10, phase 2 (%)

11. Does Promazine Syrup require special storage conditions?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (10/10).

QUESTION 11A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 81 Results of question 11a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (10/10).

QUESTION 11B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 82 Results of question 11b, phase 2 (%)

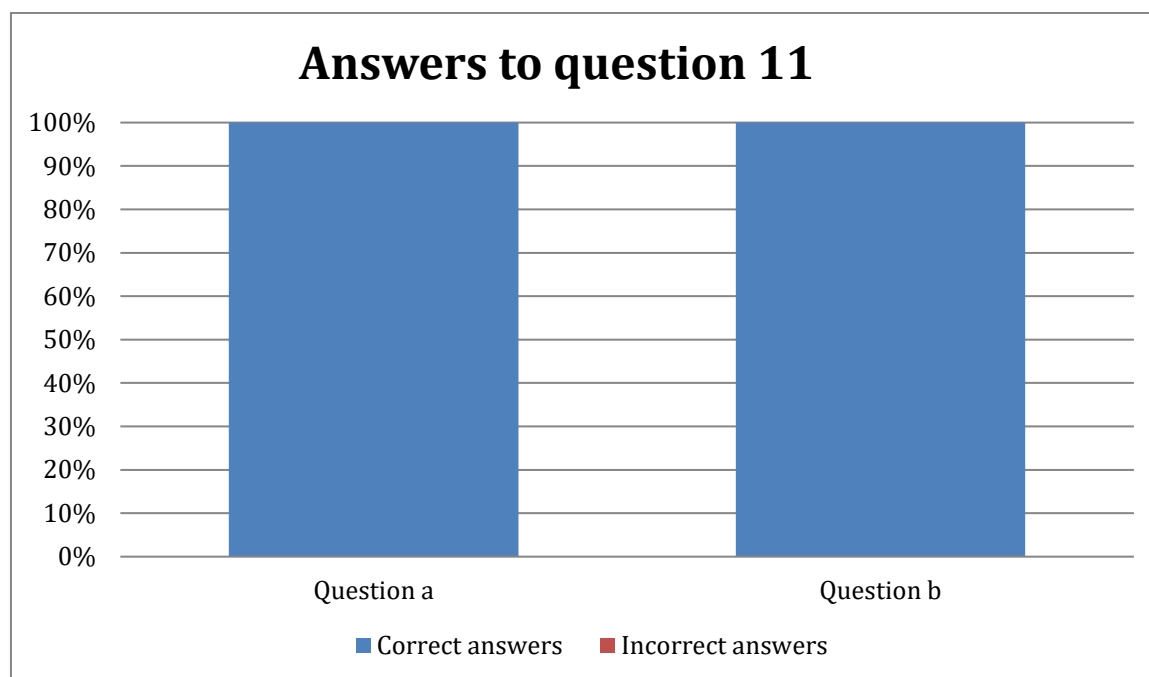


Figure 41 Correct and incorrect answers to question 11, phase 2 (%)

12. Can you use the medicinal product after the expiry date?

a) Where can the answer to this question be found in the leaflet?

100% of the participants were able to find the information in the leaflet (10/10).

QUESTION12A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 83 Results of question 12a, phase 2 (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (10/10).

QUESTION 12B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	10	100.0%	100.0%	100.0%
Total	10	100.0%		

Table 84 Results of question 12b, phase 2 (%)

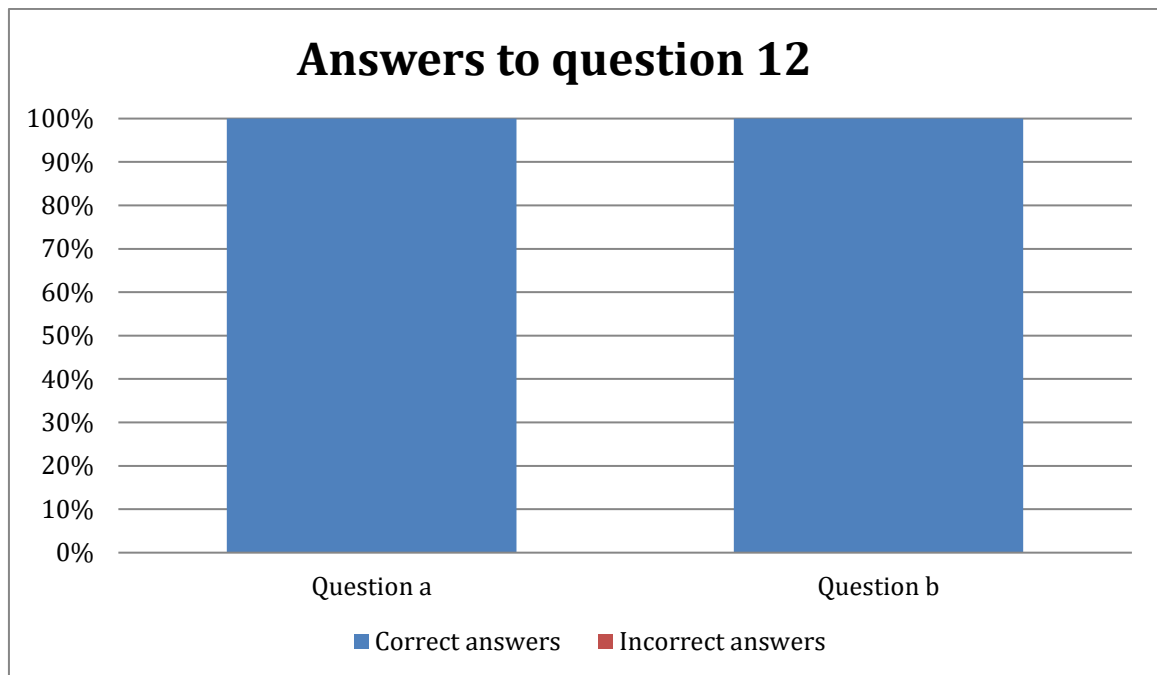


Figure 42 Correct and incorrect answers to question 12, phase 2 (%)

III. Interpretation of results for phase 2

The information for the 12 questions was correctly located in the leaflet by all volunteers and was properly understood.

For all questions, all the participants (10/10) were able to find the information in the leaflet and answer the question correctly. Therefore, **100% of the participants in phase 2 (10/10) were able to locate and understand properly the answers to questions.**

5.2. GLOBAL RESULTS

I. Characteristics of the target population

Age and gender

For the readability test (i.e. pilot phase, 1st phase and 2nd phase), 23 volunteers were recruited: 12 men and 11 women. Their ages were between 19 and 75 years old. The average age was 36.57, with a standard deviation of 17.56.

AGE

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	19	4	17.4%	17.4%	17.4%
	20	1	4.3%	4.3%	21.7%
	21	1	4.3%	4.3%	26.1%
	22	1	4.3%	4.3%	30.4%
	26	2	8.7%	8.7%	39.1%
	27	1	4.3%	4.3%	43.5%
	28	3	13.0%	13.0%	56.5%
	42	1	4.3%	4.3%	60.9%
	44	1	4.3%	4.3%	65.2%
	45	1	4.3%	4.3%	69.6%
	47	1	4.3%	4.3%	73.9%
	51	2	8.7%	8.7%	82.6%
	53	1	4.3%	4.3%	87.0%
	56	1	4.3%	4.3%	91.3%
	75	2	8.7%	8.7%	100.0%
Total		23	100.0%		

Table 85 Age of the participants*

*("válido" means "valid", "frecuencia" means "frequency", "porcentaje" means "percentage", "porcentaje válido" means "valid percentage", and "porcentaje acumulado" means "cumulative percentage").

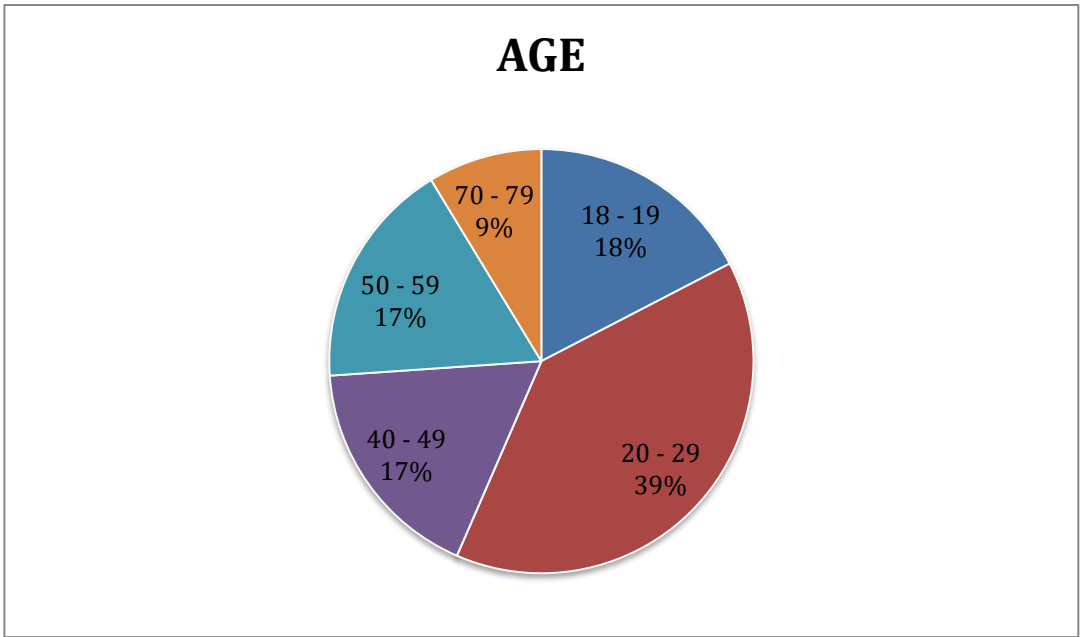


Figure 43 Age of the participants

GENDER					
		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Man	12	52.2%	52.2%	52.2%
	Woman	11	47.8%	47.8%	100.0%
Total		23	100.0%		

Table 86 Gender of the participants

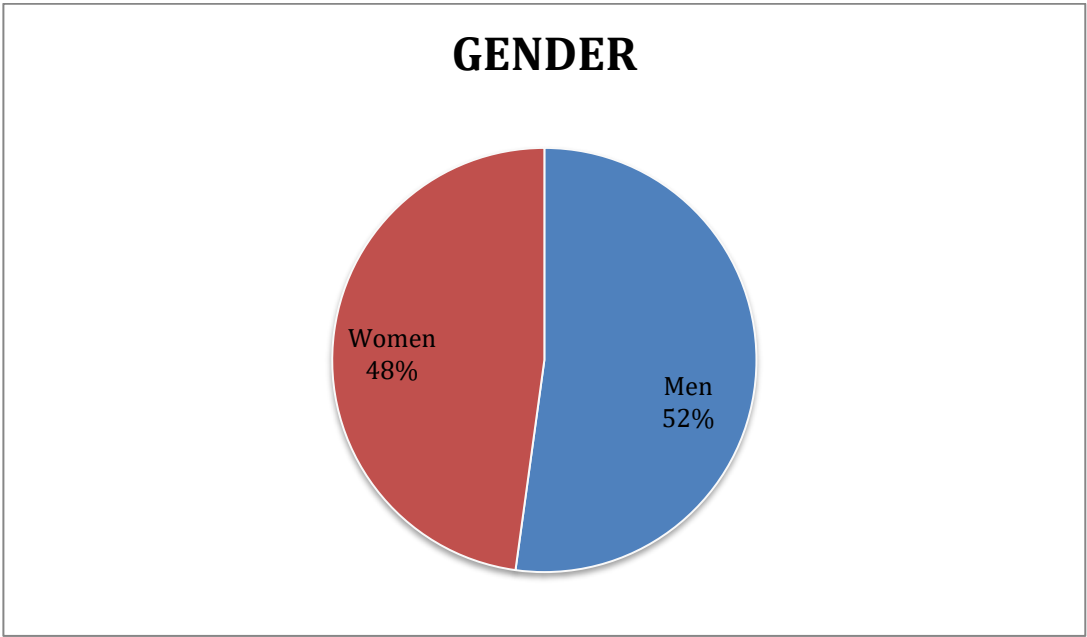


Figure 44 Gender of the participants

Level of Education

The table below summarizes the level of education of the volunteers of the study. There were 7 participants with High school level or equivalents, 4 participants with vocational training or equivalents, 1 participant with Undergraduate degree, 6 participants with a Bachelor degree and 5 with a Postgraduate degree.

LEVEL OF EDUCATION					
		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	High school level or equivalents	7	30.4%	30.4%	30.4%
	Vocational training or equivalents	4	17.4%	17.4%	47.8%
	Undergraduate degree	1	4.3%	4.3%	52.2%
	Bachelor degree	6	26.1%	26.1%	78.3%
	Postgraduate degree	5	21.7%	21.7%	100.0%
Total		23	100.0%		

Table 87 Level of Education of the participants

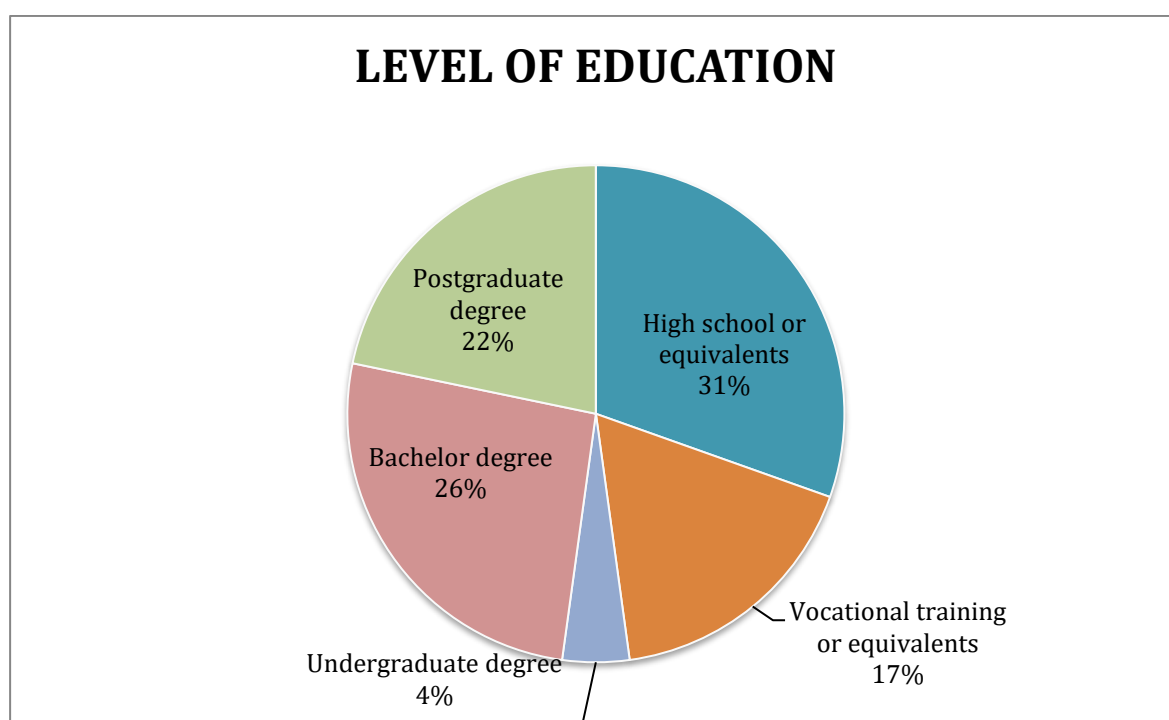


Figure 45 Level of education of the participants

Visual disorders

It is also analysed if the participants had visual disorders, such as myopia, astigmatism, hyperopia, presbyopia, etc. Information on whether they wear glasses or contact lenses to overcome the impairments is also available.

Eight volunteers (i.e. 34.8%) had visual disorders, specifically myopia (5 participants), myopia and astigmatism (2 participants) and presbyopia (1 participant). All of them but one wear glasses or contact lenses to solve the problems.

VISUAL DISORDERS

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido NO	15	65.2%	65.2%	65.2%
YES	8	34.8%	34.8%	100.0%
Total	23	100.0%		

Table 88 Visual disorders of the participants

II. Results of the readability test

Below are the percentages of hits and mistakes for the 12 questions of the readability test. Each question has 2 sections: section “a” determines the ability to locate the answer in the leaflet, and section “b” evaluates the ability to understand the answer given in the leaflet and express it in their own words.

1. What Promazine Syrup used for?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (23/23).

QUESTION 1A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 89 Results of question 1a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (23/23).

QUESTION 1B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 90 Results of question 1b (%)

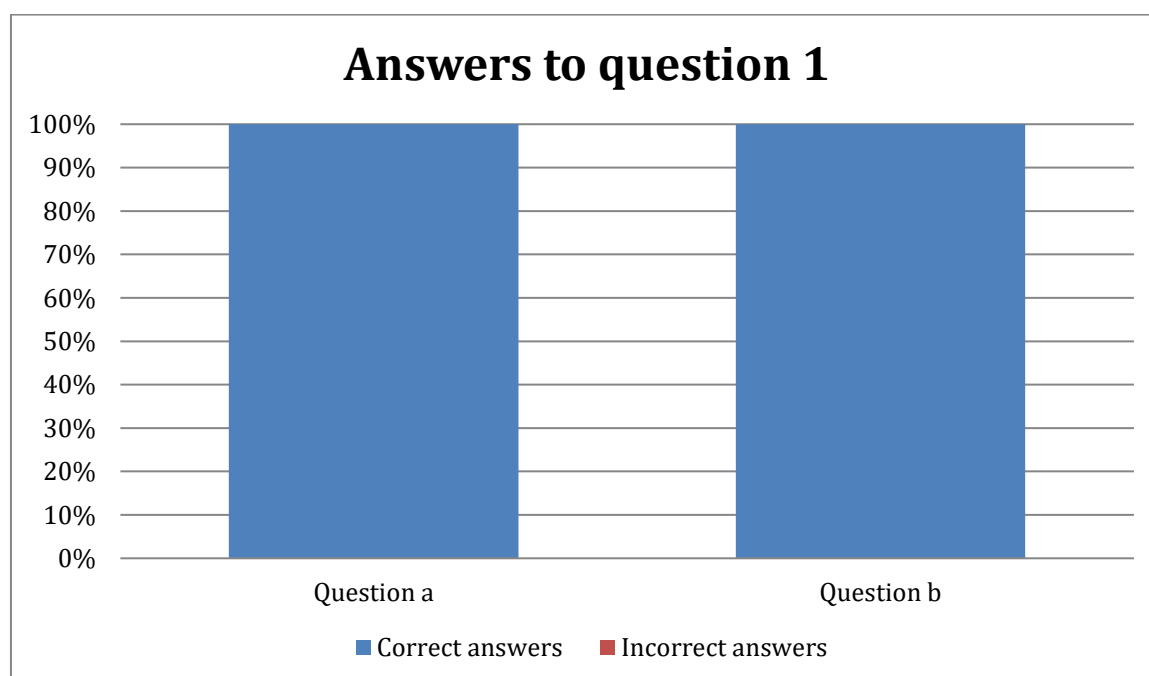


Figure 46 Correct and incorrect answers to question 1 (%)

2. Can you take Promazine Syrup if you are allergic to promazine?

a) Where can the answer to this question be found in the leaflet?

100% of the participants found the answer in the leaflet (23/23).

QUESTION 2A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 91 Results of question 2a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants were able to answer correctly the question in their own words (23/23).

QUESTION 2B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 92 Results of question 2b (%)

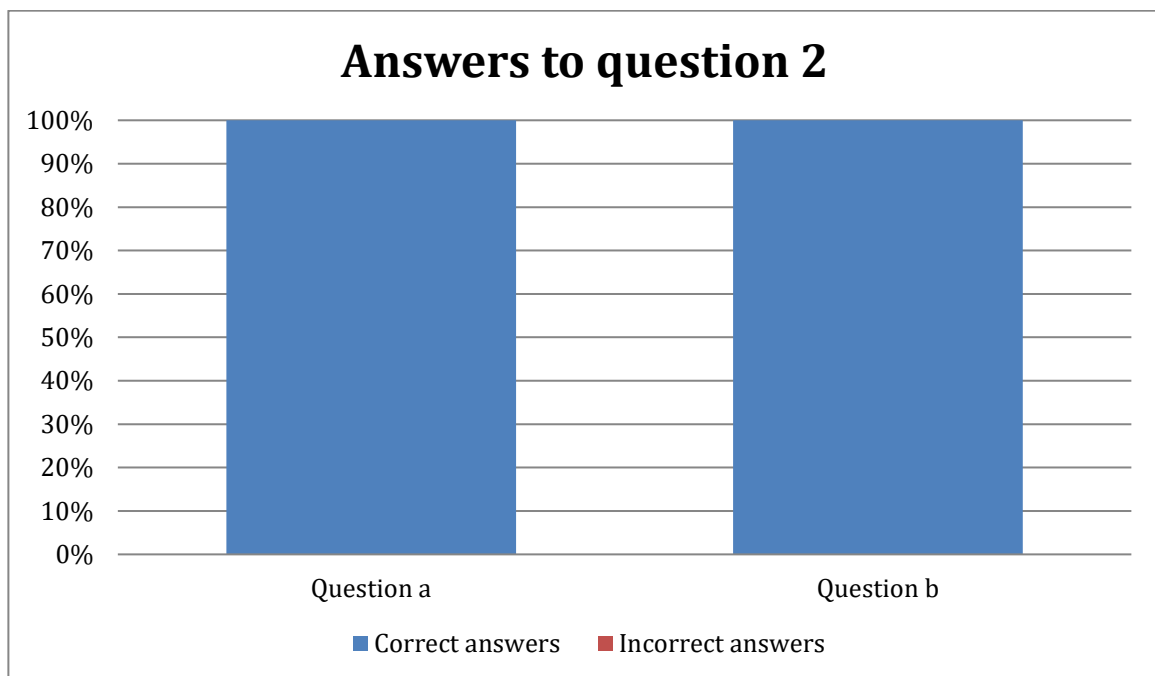


Figure 47 Correct and incorrect answers to question 2 (%)

3. Can you take Promazine Syrup if you have bone marrow depression?

a) Where can the answer to this question be found in the leaflet?

100% of the participants were able to correctly locate the answer in the leaflet (23/23).

QUESTION 3A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 93 Results of question 3a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (23/23).

QUESTION 3B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 94 Results of question 3b (%)

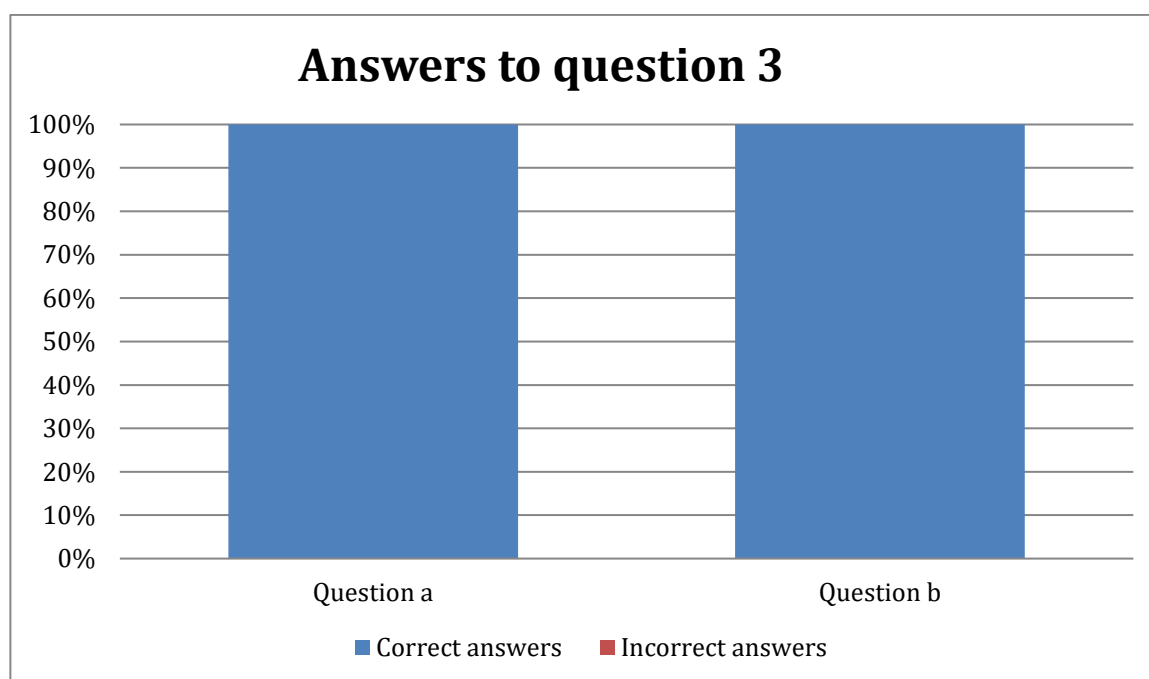


Figure 48 Correct and incorrect answers to question 3 (%)

4. Can a patient breast-feed take Promazine Syrup without ask a doctor?

a) Where can the answer to this question be found in the leaflet?

100% of the participants found the answer in the leaflet (23/23).

QUESTION 4A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 95 Results of question 4a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (23/23).

QUESTION 4B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 96 Results of question 4b (%)

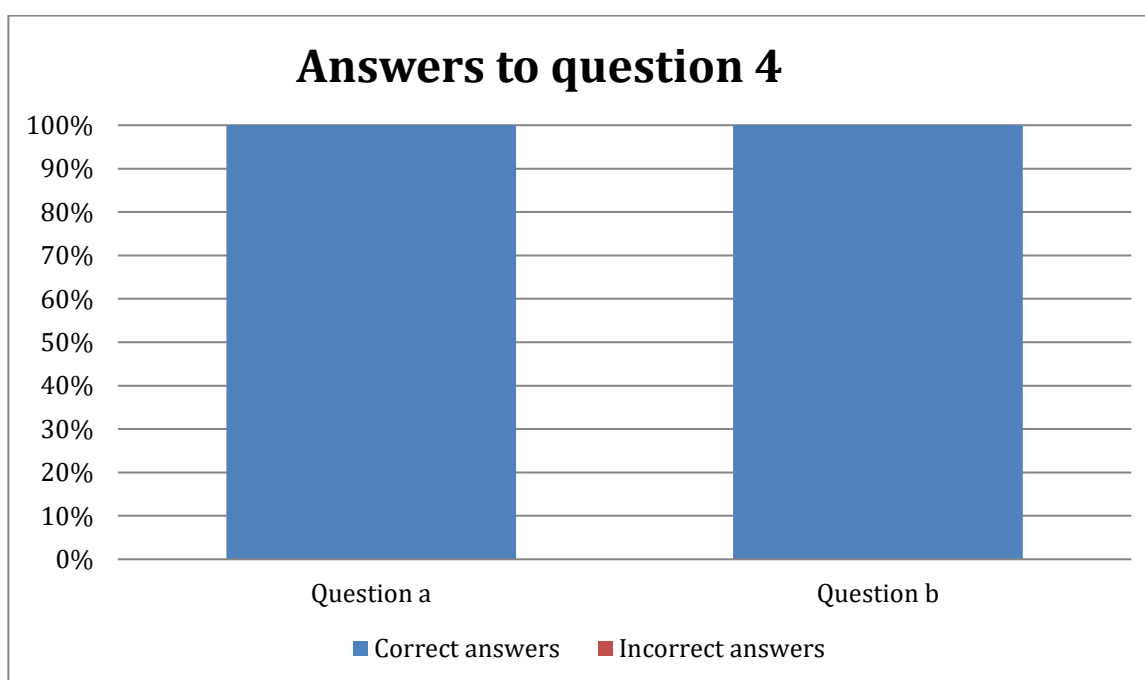


Figure 49 Correct and incorrect answers to question 4 (%)

5. What is the recommended dose for Promazine Syrup in adults?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (23/23).

QUESTION 5A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 97 Results of question 5a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (23/23).

QUESTION 5B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 98 Results of question 5b (%)

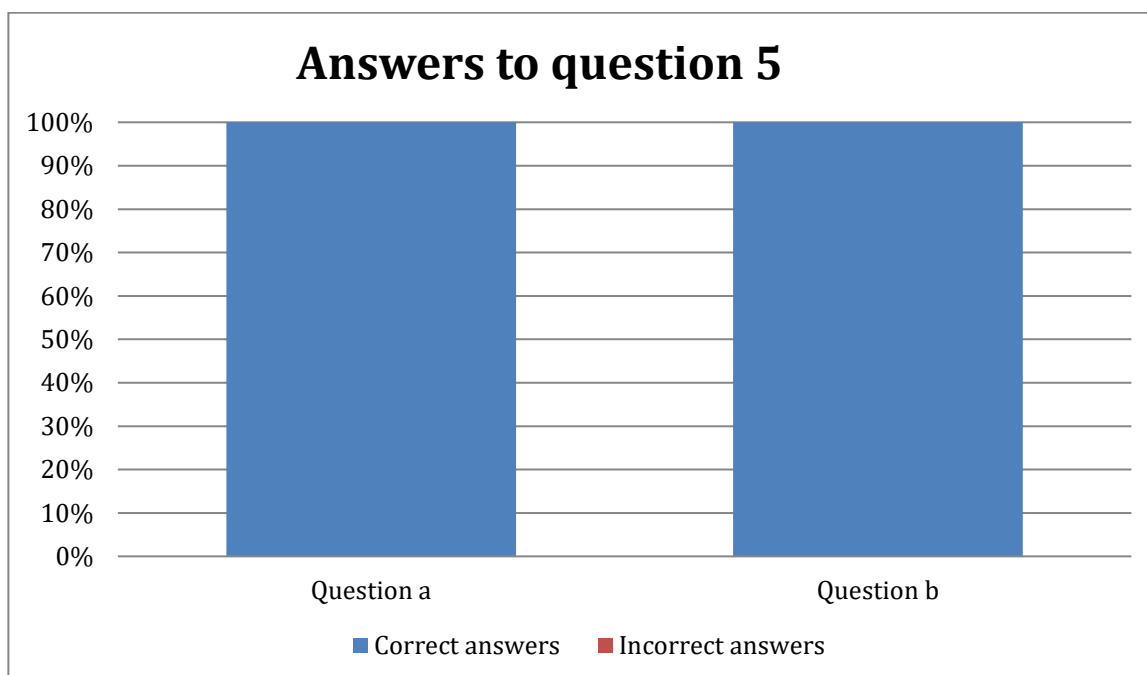


Figure 50 Correct and incorrect answers to question 5 (%)

6. Can you drive if you are under Promazine Syrup treatment?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (23/23).

QUESTION 6A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 99 Results of question 6a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (23/23).

QUESTION 6B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 100 Results of question 6b (%)

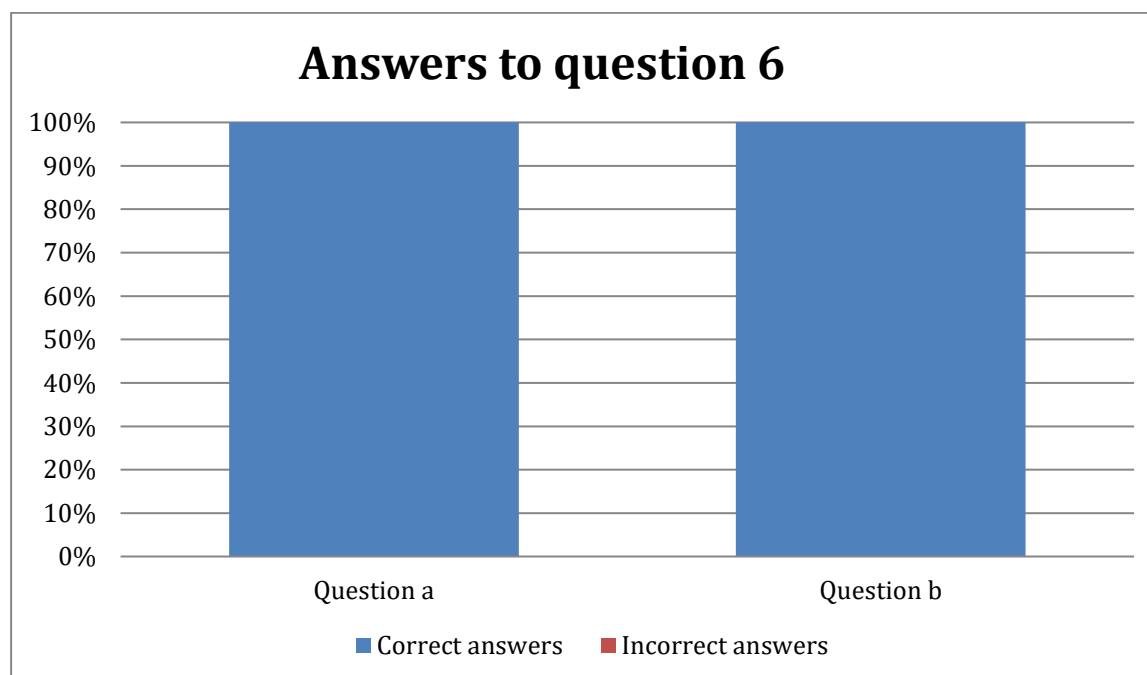


Figure 51 Correct and incorrect answers to question 6 (%)

7. Can you take alcohol if you take Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants could find the answer in the leaflet (23/23).

QUESTION 7A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 101 Results of question 7a (%)

b) If possible, write in your own words the answer to the question.

100 % of the participants understood the information and could answer the question in their own words (23/23).

QUESTION 7B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 102 Results of question 7b (%)

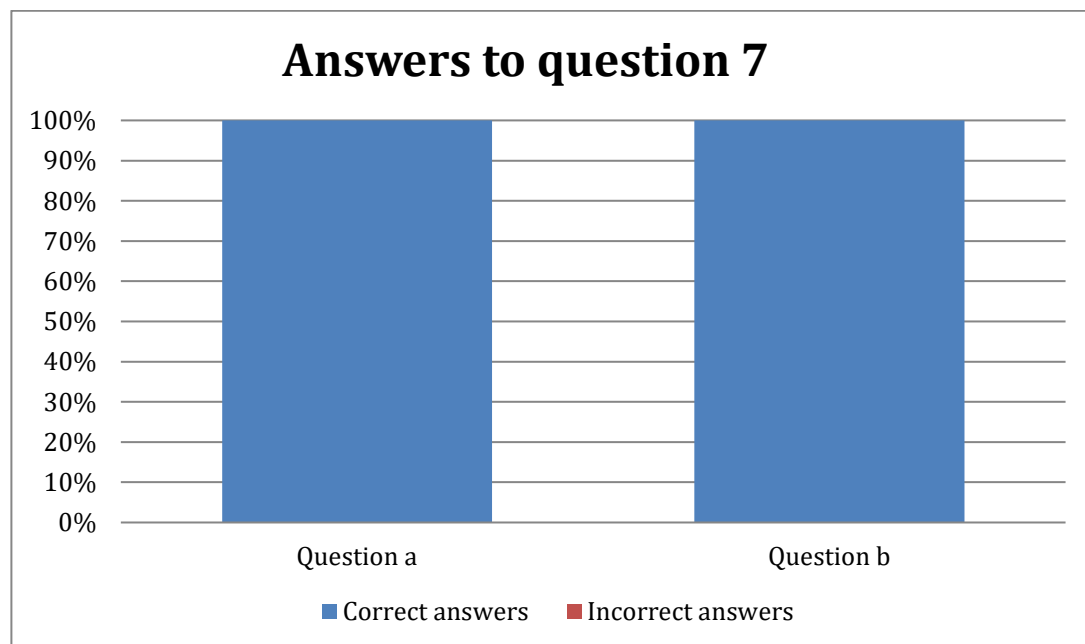


Figure 52 Correct and incorrect answers to question 7 (%)

8. What should you do if you take more Promazine Syrup than you should?

a) Where can the answer to this question be found in the leaflet?

100 % of the participants correctly found the answer in the leaflet (23/23).

QUESTION 8A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 103 Results of question 8a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer in their own words (23/23).

QUESTION 8B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 104 Results of question 8b (%)

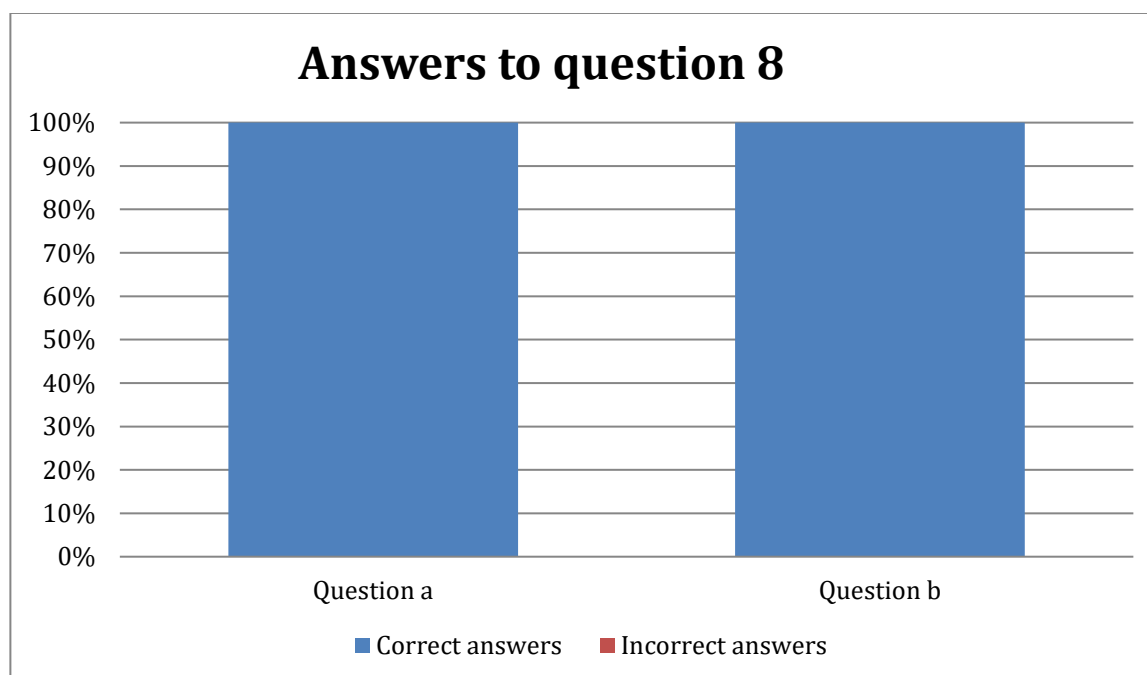


Figure 53 Correct and incorrect answers to question 8 (%)

9. Can the children use Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (23/23).

QUESTION 9A

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 105 Results of question 9a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and could answer the question in their own words (23/23).

QUESTION 9B

	Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido Correct	23	100.0%	100.0%	100.0%
Total	23	100.0%		

Table 106 Results of question 9b (%)

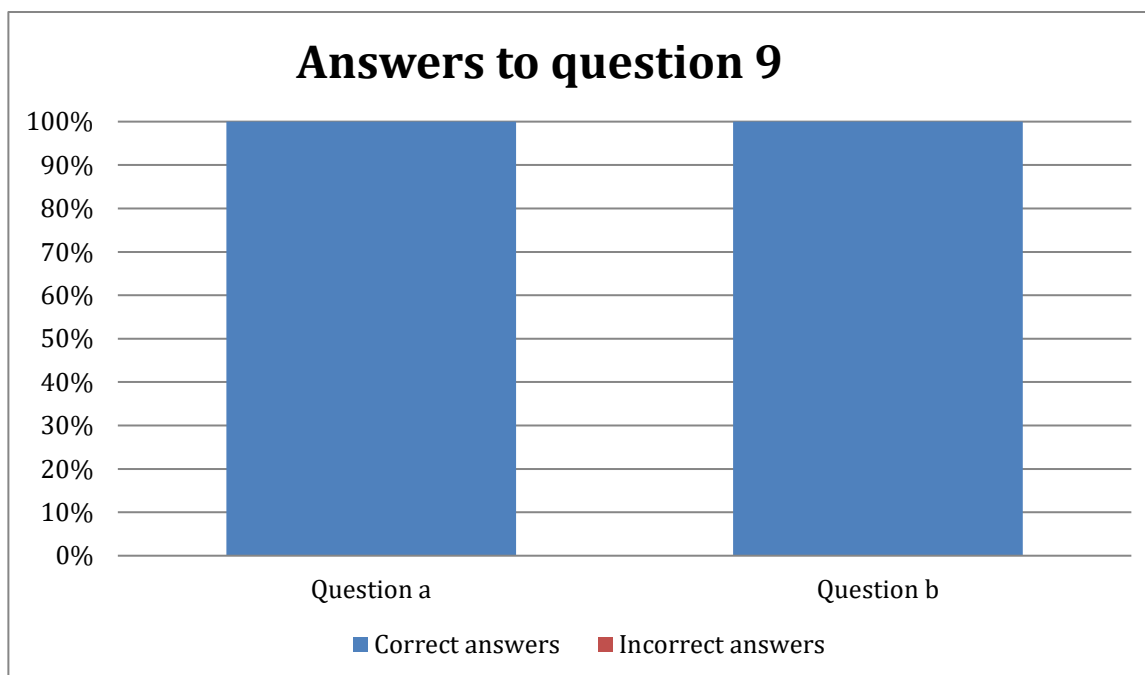


Figure 54 Correct and incorrect answers to question 9 (%)

10. What should you do if you get any side effect after using Promazine Syrup?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (23/23).

QUESTION 10A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 107 Results of question 10a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and could answer in their own words (23/23).

QUESTION 10B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 108 Results of question 10b (%)

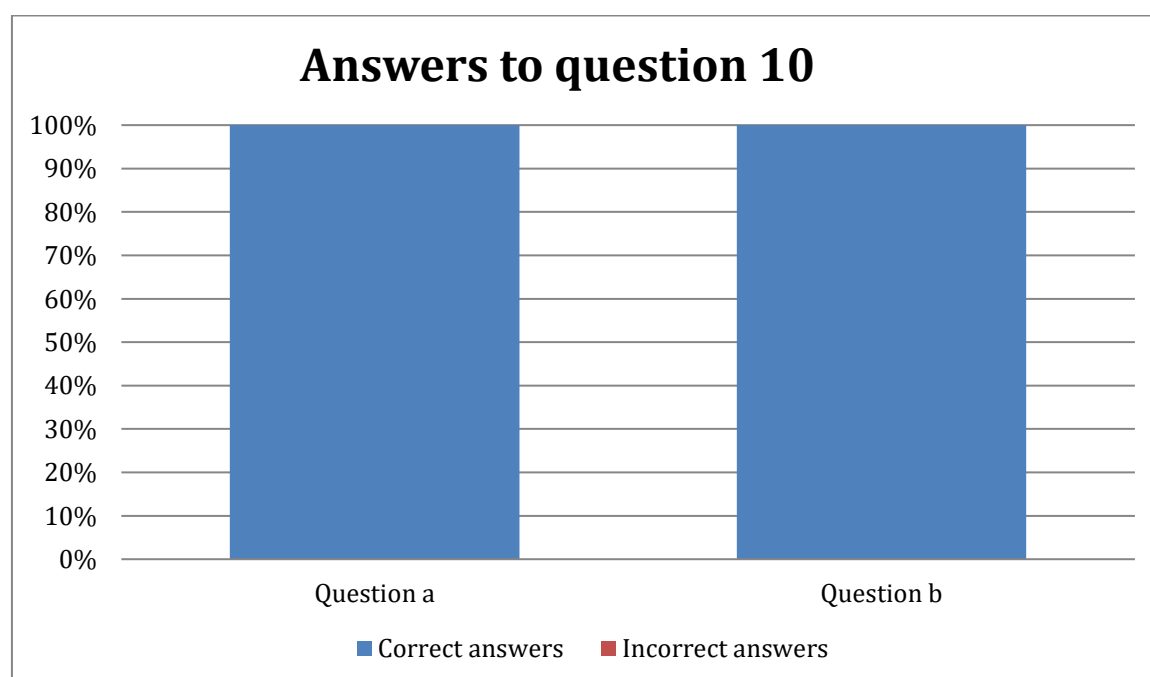


Figure 55 Correct and incorrect answers to question 10 (%)

11. Does Promazine Syrup require special storage conditions?

a) Where can the answer to this question be found in the leaflet?

100% of the participants correctly located the answer in the leaflet (23/23).

QUESTION 11A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 109 Results of question 11a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the answer and were able to answer the question in their own words (23/23).

QUESTION 11B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 110 Results of question 11b (%)

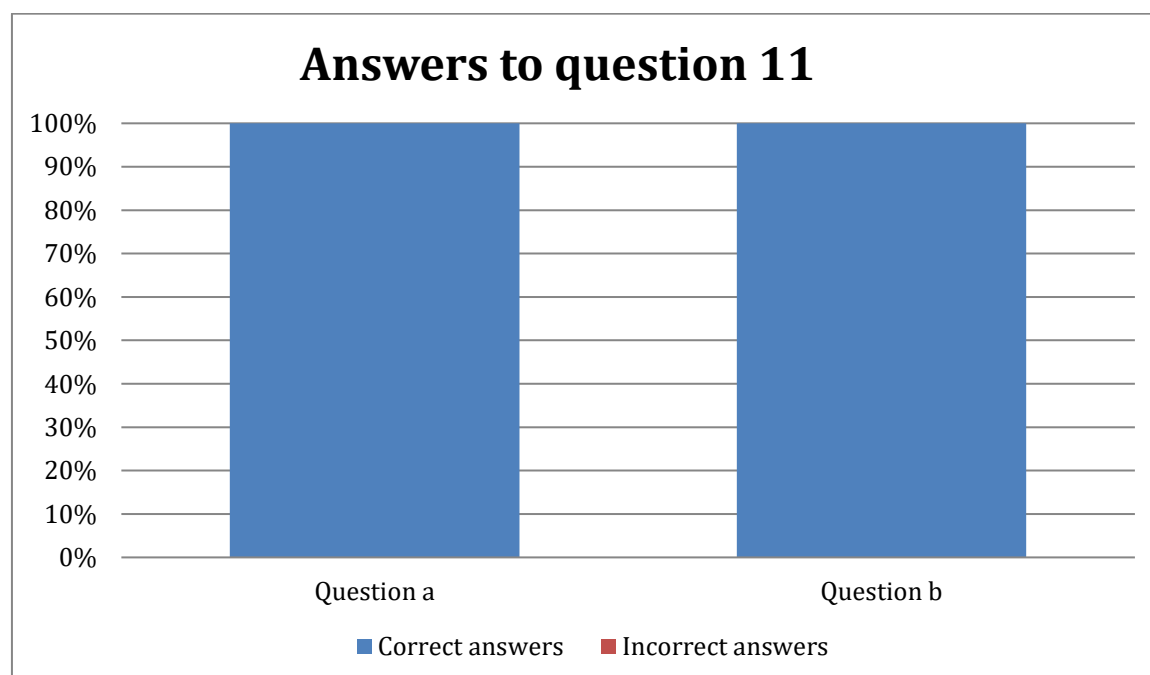


Figure 56 Correct and incorrect answers to question 11 (%)

12. Can you use the medicinal product after the expiry date?

a) Where can the answer to this question be found in the leaflet?

100% of the participants were able to find the information in the leaflet (23/23).

QUESTION 12A

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 111 Results of question 12a (%)

b) If possible, write in your own words the answer to the question.

100% of the participants understood the information and were able to answer the question in their own words (23/23).

QUESTION 12B

		Frecuencia	Porcentaje	Porcentaje Válido	Porcentaje Acumulado
Válido	Correct	23	100.0%	100.0%	100.0%
Total		23	100.0%		

Table 112 Results of question 12b (%)

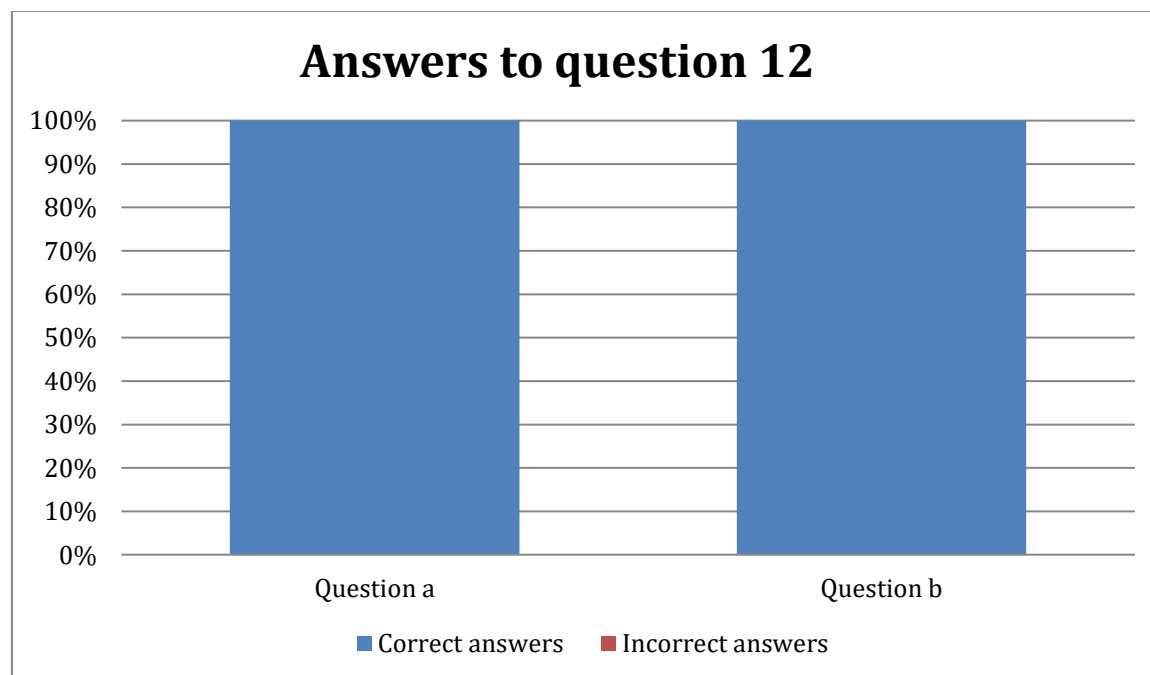


Figure 57 Correct and incorrect answers to question 12 (%)

III. Interpretation of results

The information for the 12 questions was correctly located in the leaflet by the volunteers and was properly understood.

For all the questions, all the participants (23/23) were able to find the information in the leaflet. Therefore, **100% of the participants in the test (23/23) were able to locate the answer and 100% were able to understand the information and answer correctly in their own words.**

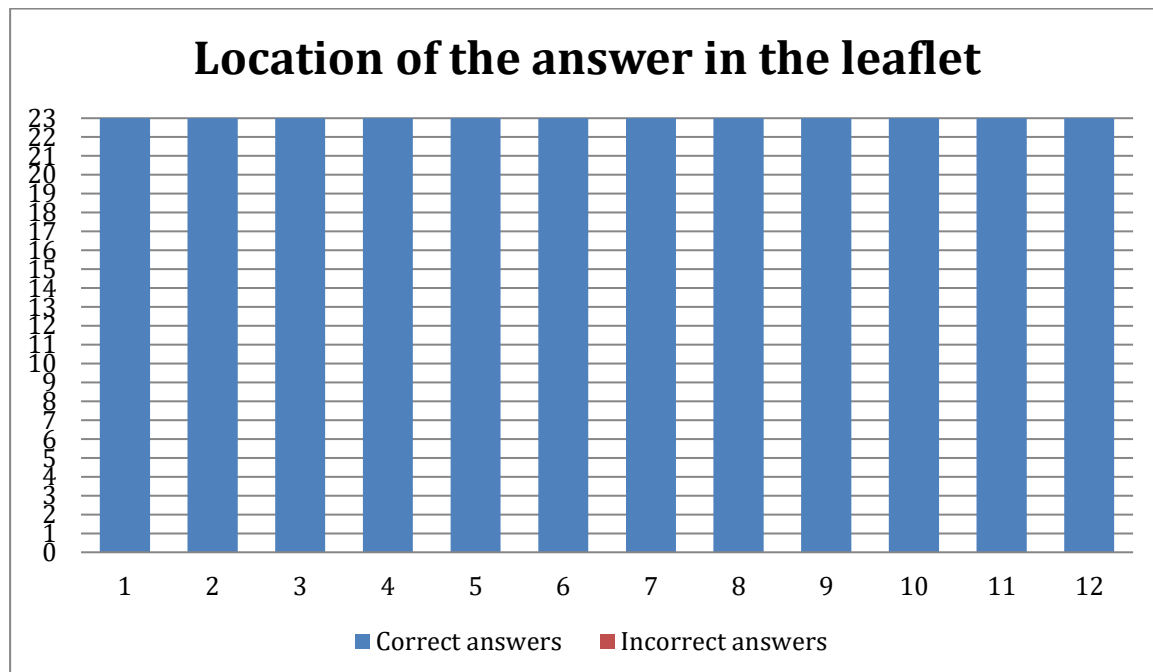


Figure 58 Location of the answers in the leaflet (Number of volunteers vs. questions)

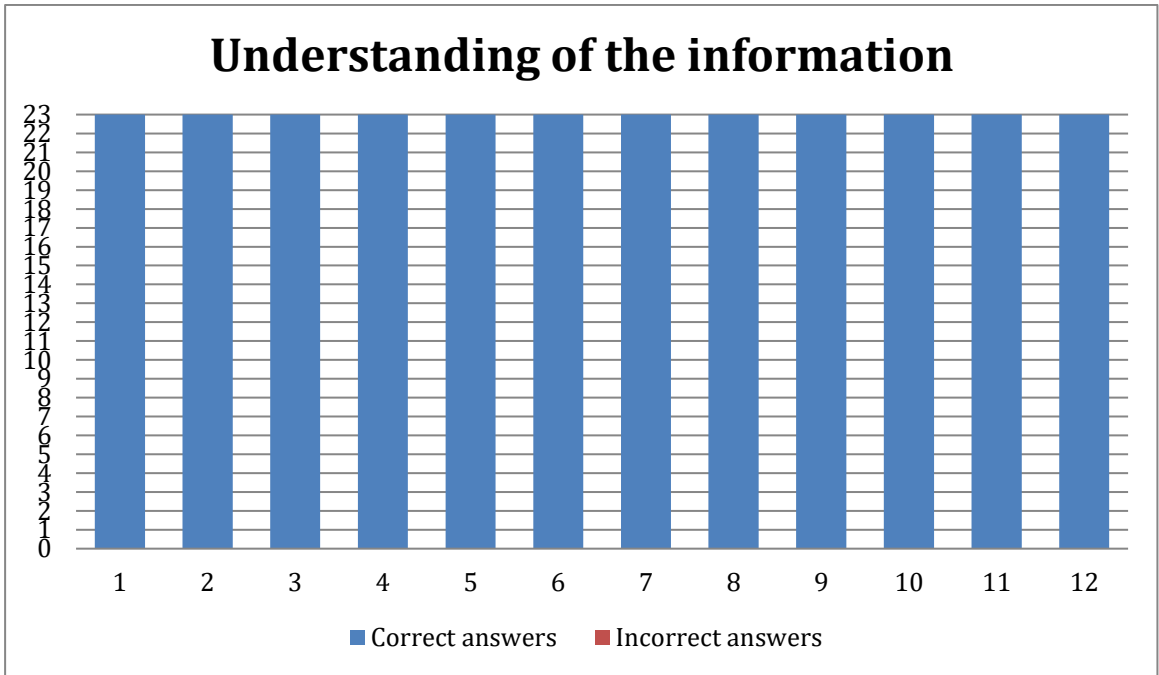
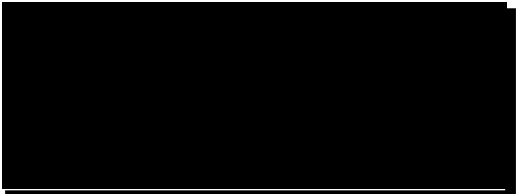


Figure 59 Understanding of the information provided in the leaflet (Number of volunteers vs. questions)

6. CONCLUSIONS

From the readability user test of leaflet for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup, it is right to conclude that:

- The test was carried out on 23 volunteers (3 in pilot phase, 10 in phase 1 and 10 in phase 2) with ages between 19 and 75 years old and level of education of High school level or equivalents and higher. 47.8% (11/23) are women.
- 34.8% of the volunteers (8/23) have visual disorders and all of them wear glasses or contact lenses to solve the problems.
- 100% of the participants (23/23) could find the answer to all the questions in the leaflet (section “a”) and 100% answered correctly and in their own words all the questions (section “b”). Therefore **100% of the participants (23/23) were able to locate the information in the leaflet and 100% (23/23) answered all the questions properly.**

In conclusion, the evaluated leaflet is considered adequate, since it MEETS the requirements set out in “Guideline on the readability of the labelling and package leaflet of medicinal products for human use. Revision1, 12 January 2009”.

7. ANNEXES

7.1. READABILITY TEST

Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup

1. What Promazine Syrup used for?
2. Can you take Promazine Syrup if you are allergic to promazine?
3. Can you take Promazine Syrup if you have bone marrow depression?
4. Can a patient breast-feed take Promazine Syrup without ask a doctor?
5. What is the recommended dose for Promazine Syrup in adults?
6. Can you drive if you are under Promazine Syrup treatment?
7. Can you take alcohol if you take Promazine Syrup?
8. What should you do if you take more Promazine Syrup than you should?
9. Can the children use Promazine Syrup?
10. What should you do if you get any side effect after using Promazine Syrup?
11. Does Promazine Syrup require special storage conditions?
12. Can you use the medicinal product after the expiry date?

7.2. EVALUATION OF THE READABILITY TEST

The evaluation of the answers to each of the questions in the readability test will be carried out by assessing the following aspects:

1. Ability to locate the answer in the leaflet.
2. Ability to understand the answer given in the package leaflet and to express it in one's own words.

The answers to the readability test for Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup shall be considered correct if they match or are similar to those given below:

1. What Promazine Syrup used for?

Section 1 "What Promazine Syrup is and what it is used for".

The name of your medicine is Promazine Hydrochloride Oral Syrup (referred to as Promazine Syrup in this leaflet). It contains promazine hydrochloride which belongs to a group of medicines called phenothiazines.

Promazine can be used to calm your emotions particularly if you feel restless and agitated, particularly if you are an older person.

2. Can you take Promazine Syrup if you are allergic to promazine?

Section 2. "What you need to know before you take Promazine Syrup". Specifically, in "Do not take Promazine Syrup"

Do not take Promazine Syrup:

- if you are allergic to promazine or medicines like promazine or any other ingredients in this liquid (listed in section 6). The signs of an allergic reaction can include a rash, itching or shortness of breath.

3. Can you take Promazine Syrup if you have bone marrow depression?

Section 2. "What you need to know before you take Promazine Syrup". Specifically, in "Do not take Promazine Syrup".

Do not take Promazine Syrup:

- If you have bone marrow depression. This means that your immune system is not working as well as usual. Your body will find it harder to fight infection

4. Can a patient breast-feed take Promazine Syrup without ask a doctor?

Section 2. "What you need to know before you take Promazine Syrup". Specifically, in "Do not take Promazine Syrup"

Do not take Promazine Syrup:

- If you are pregnant or breast-feeding
or "Pregnancy and breast-feeding"

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not use this medicine if you are pregnant or breast-feeding unless your doctor feels it is absolutely necessary.

The following symptoms may occur in newborn babies of mothers that have used promazine in the last three months of their pregnancy: shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor

5. What is the recommended dose for Promazine Syrup in adults?

Section 3 "How to take Promazine Syrup". Specifically, in "Adults"

The recommended dose for adults is 100mg to 200mg four times a day.

The dose prescribed and how often you should take the doses will depend upon the condition being treated and on your response. You will start treatment on a low dose which will be increased as necessary by your doctor.

6. Can you drive if you are under Promazine Syrup treatment?

Section 2. "What you need to know before you take Promazine Syrup". Specifically, in "Driving and using machines".

Do not drive or use tools or machines if this medicine makes you drowsy or gives you blurred vision.

When using this medicine, alcohol and some other medicines may make you feel more drowsy than usual.

7. Can you take alcohol if you take Promazine Syrup?

Section 2. "What you need to know before you take Promazine Syrup". Specifically, in "Promazine Syrup with food, drink and alcohol".

You must not drink alcohol whilst taking this medicine. This is because this medicine may make you feel drowsy and drinking alcohol will make you even more drowsy. Drinking alcohol may also affect the condition you are suffering from.

8. What should you do if you take more Promazine Syrup than you should?

Section 3 "How to take Promazine Syrup", specifically in "If you take more Promazine Syrup than you should"

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. Signs of an overdose may include deep sleep, feeling agitated, feeling excited, fits and coma.

9. Can the children use Promazine Syrup?

Section 3 "How to take Promazine Syrup", specifically in "Children"

This product should not be given to children.

10. What should you do if you get any side effect after using Promazine Syrup?

Section 4 "Possible side effects", specifically in "Reporting of side effects".

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

11. Does Promazine Syrup require special storage conditions?

Section 5 "How to store Promazine Syrup"

Store below 25°C. Protect from light.

12. Can you use the medicinal product after the expiry date?

Section 5 "How to store Promazine Syrup".



Do not use this medicine after the expiry date which is stated on the label and carton (EXP: month, year). The expiry date refers to the last day of that month.

7.3. INFORMATION SHEET FOR THE VOLUNTEER

INFORMATION SHEET FOR THE VOLUNTEER
LEAFLET READABILITY TEST FOR THE MEDICINAL PRODUCT PROMAZINE HYDROCHLORIDE 25MG/5ML & 50MG/5ML ORAL SYRUP

SPONSOR OF THE STUDY: Aristo Pharma GmbH.

INTRODUCTION

We are writing to inform you about the readability test in which you are invited to participate.

Our intention is that you receive correct and sufficient information so that you can evaluate and judge whether or not you want to participate in this study. To do this, please read this fact sheet carefully. Any questions that may arise will be clarified after the explanation. In addition, you can consult with the people you consider appropriate.

VOLUNTARY PARTICIPATION

You should be aware that your participation in this readability test is voluntary and that you can decide not to participate, or to change your decision and withdraw your consent at any time.

GENERAL DESCRIPTION OF THE READABILITY TEST

This study is a leaflet readability test for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup.

The aim of this test is to study whether the package leaflet of this medicine is easily understood by their potential users, for which your collaboration is requested.

USED METHODOLOGY

Once you have read and understood this information sheet, you will be asked to sign the "Informed Consent", by which you will give your written agreement to participate in the readability test.

A face-to-face interview will be conducted with the Investigator in charge of the test.

First, you will be asked to read carefully the leaflet under evaluation. You will be given a test which you will be asked to complete according to the instructions of the Researcher.

Two aspects of your answers will be assessed: the ease of finding the information requested and the ability to understand the answer found.

CONFIDENTIALITY OF THE DATA

All information recorded about you will be kept strictly confidential, in accordance with the Spanish Data Protection Act (Ley Orgánica de Protección de Datos). The results of the test will always be presented in a global form and never, under any circumstances, on an individual basis, in order to guarantee your rights regarding the confidentiality of your personal data.

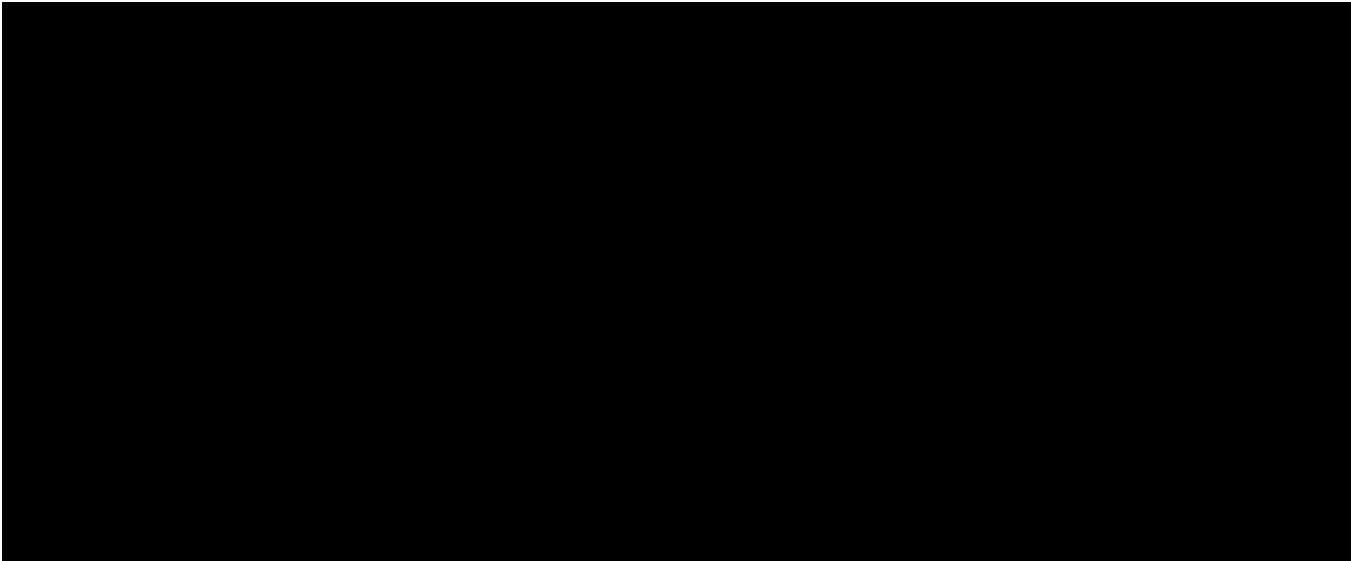
ECONOMIC COMPENSATION

[REDACTED]

LOCATION WHERE THE STUDY IS PERFORMED

The study will be performed in the following address:

[REDACTED]



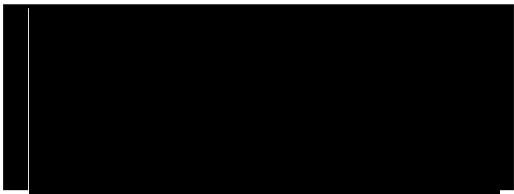
INFORMED CONSENT
LEAFLET READABILITY TEST FOR THE MEDICINAL PRODUCT PROMAZINE HYDROCHLORIDE 25MG/5ML & 50MG/5ML ORAL SYRUP

- ✓ I have read the information sheet that was given to me.
- ✓ I was able to ask questions about the readability test.
- ✓ I have received sufficient information about the readability test.
- ✓ I have spoken to the Principal Investigator.
- ✓ I understand that my participation is voluntary and without financial compensation.
- ✓ I understand that I can withdraw from the test:
 1. Whenever I want.
 2. Without having to explain myself.

I therefore freely agree to participate in the readability test of the package leaflet for the medicinal product Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup.

Signature of the participants _____ Date: _____

Signature of the Investigator _____ Date: _____



7.5. TEXT OF THE LEAFLET UNDER EVALUATION

Promazine Hydrochloride 25mg/5ml & 50mg/5ml Oral Syrup

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Promazine Syrup is and what it is used for
2. What you need to know before you take Promazine Syrup
3. How to take Promazine Syrup
4. Possible side effects
5. How to store Promazine Syrup
6. Contents of the pack and other information

1. What Promazine Syrup is and what it is used for

The name of your medicine is Promazine Hydrochloride Oral Syrup (referred to as Promazine Syrup in this leaflet). It contains promazine hydrochloride which belongs to a group of medicines called phenothiazines.

Promazine can be used to calm your emotions particularly if you feel restless and agitated, particularly if you are an older person.

2. What you need to know before you take Promazine Syrup

Do not take Promazine Syrup:

- if you are allergic to promazine or medicines like promazine or any other ingredients in this liquid (listed in section 6). The signs of an allergic reaction can include a rash, itching or shortness of breath
- if you are pregnant or breast-feeding
- if you have bone marrow depression. This means that your immune system is not working as well as usual. Your body will find it harder to fight infection
- if you have a tumour of your adrenal gland that causes high blood pressure (phaeochromocytoma)
- if you have dulled senses such as feeling sleepy or uncoordinated, having blurred vision, slurred speech or being less aware of your surroundings (CNS depression).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Promazine Syrup.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Promazine Syrup if,

- you have liver problems or a history of jaundice (yellowing of the skin and whites of the eyes)
- you have a history of blood problems including low levels of potassium or magnesium
- you or someone else in your family has a history of blood clots, as medicines like these have been associated
- with formation of blood clots
- you have heart problems including unusual heart beats, heart disease or heart failure
- you have lung and breathing problems
- you have kidney problems
- you have Parkinson's Disease
- you have had a stroke or you have any of the following that can increase your risk of having a stroke
 - a heart attack
 - a TIA (transient ischaemic attack). This is a type of stroke where symptoms last less than 24 hours
 - an artificial heart valve
 - uncontrolled high blood pressure
 - diabetes
 - high cholesterol
 - a family history of strokes
 - you smoke
 - you drink excess alcohol (this tends to weaken blood vessels and can raise blood pressure)
- you have epilepsy
- you have or have had in the past narrow angle glaucoma (this is abnormal pressure in the eye accompanied by pain and blurred vision)
- you have an underactive thyroid
- you have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- you have an enlarged prostate gland
- older people should take promazine with caution in very hot or cold weather. This is because there is a risk of having a higher body temperature than usual in hot weather (hyperthermia) and a lower body temperature in cold weather (hypothermia) if you take this medicine
- you are going to have an anaesthetic; tell your doctor or dentist that you are taking promazine.

Other important information to take into account before you take this medicine:

- if you or members of your family have heart problems (including heart failure, heart attack or uneven heart beats) or you have low potassium or magnesium in your blood, your doctor may do some tests on your heart and blood before giving you this medicine
- your doctor may also want to give you regular blood and eye tests during your treatment
- do not go into direct sunlight if you are taking high doses of this medicine. This is because you may become more sensitive to strong sunlight while taking this medicine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Promazine Syrup.

Other medicines and Promazine Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because promazine can affect the way some other medicines work. Also some medicines can affect the way promazine works.

Tell your doctor if you are taking any of these medicines:

- heart medicines such as quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, bretylium
- medicines to treat high blood pressure
- medicines that control your emotions such as chlorpromazine, trifluoperazine, antidepressants such as amitriptyline and maprotiline, pimozone, sertindole, haloperidol, lithium, MAOIs (Monoamine Oxidase Inhibitors), reboxetine
- medicines that dull the senses such as sleeping tablets
- medicines to treat epilepsy
- medicines used to treat malaria such as quinine and mefloquine
- antibiotics such as sparfloxacin, moxifloxacin and intravenous erythromycin
- medicines used to treat Parkinson's Disease such as levodopa
- medicines to treat allergies such as hayfever (antihistamines) for example terfenadine
- medicines used to treat stomach problems such as cimetidine and cisapride
- medicines to treat diabetes, for example, chlorpropamide, glibenclamide, gliclazide or tolbutamide
- strong painkillers such as codeine
- medicines used to stop the body producing red blood cells such as carbamazepine, co-trimoxazole, chloramphenicol, sulphonamides, pyralizone, azapropazone, penicillamine and cytotoxics (used in cancer treatment)
- medicines that help the body get rid of water and affect electrolyte balance (diuretics) such as furosemide or indapamide
- metoclopramide, used to treat nausea (feeling sick) and vomiting
- tetrabenazine, used to treat disorders that cause unnatural movements
- ritonavir, used to treat HIV and AIDS
- tramadol, used to treat pain
- sympathomimetics, medicines that copy the effects of substances such as adrenaline that naturally occur in the body, for example, salbutamol or pseudoephedrine.
- memantine, used to treat Alzheimer's disease
- kaolin, used to treat diarrhoea.

Promazine Syrup with food, drink and alcohol

You must not drink alcohol whilst taking this medicine. This is because this medicine may make you feel drowsy and drinking alcohol will make you even more drowsy. Drinking alcohol may also affect the condition you are suffering from.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not use this medicine if you are pregnant or breast-feeding unless your doctor feels it is absolutely necessary.

The following symptoms may occur in newborn babies of mothers that have used promazine in the last three months of their pregnancy: shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

Do not drive or use tools or machines if this medicine makes you drowsy or gives you blurred vision.
When using this medicine, alcohol and some other medicines may make you feel more drowsy than usual.

Promazine Syrup contains methyl-, ethyl- and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Promazine Syrup contains propylene glycol

This medicine contains 500 mg propylene glycol in each 5ml.

Promazine Syrup contains glucose

This medicine contains 1.75 g glucose in each 5ml. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Glucose may be harmful to teeth.

Promazine Syrup contains sucrose

This medicine contains 1.5g sucrose in each 5ml. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Sucrose may be harmful to teeth.

3. How to take Promazine Syrup

Always take this medicine exactly as your doctor or pharmacist has told you. Look on the label and check with your doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 25mg or 50mg of promazine hydrochloride in each 5ml
- take this medicine by mouth
- if you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

Adults

- The recommended dose for adults is 100mg to 200mg four times a day
- The dose prescribed and how often you should take the doses will depend upon the condition being treated and on your response. You will start treatment on a low dose which will be increased as necessary by your doctor

Elderly

- Older people will be given a lower dose. Your doctor will gradually increase this dose.

Children

This product should not be given to children.

If you take more Promazine Syrup than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. Signs of an overdose may include deep sleep, feeling agitated, feeling excited, fits and coma.

If you forget to take Promazine Syrup

- Do not take a double dose (two doses at the same time) to make up for forgotten doses
- Skip the missed dose then go on as before.

If you stop taking Promazine Syrup

Keep taking Promazine Syrup until your doctor tells you to stop. The doctor will lower your dose gradually.

If you stop taking the medicine suddenly you may get withdrawal symptoms. Signs include:

- feeling or being sick, sweating and difficulty sleeping (insomnia)
- your original symptoms becoming worse
- movements that you can't control.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, promazine can cause side effects, although not everybody gets them.

Stop taking the medicine straight away and see your doctor if:

- **you have an allergic reaction to promazine syrup**
An allergic reaction may include any kind of skin rash, flaking skin, boils or sore lips and mouth, sudden wheezing, fluttering or tightness of the chest or collapse.
- **you have any of the following symptoms:**
 - unusually fast heart beat, unstable blood pressure (feeling dizzy, light-headed or faint) and sweating. These are early warning signs of a disorder caused by the type of medicine you are taking
 - very high body temperature, muscle stiffness or a change in consciousness leading to coma
 - yellowing of the skin and whites of your eyes (jaundice) with fever and possible liver damage.

If you get any of the following side effects, see your doctor as soon as possible:

- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately
- lack of emotion
- fits
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness, yellowing of the skin, weakness or breathlessness
- heart changes including fast heart beats, unusual heart beats, heart attack. Symptoms of a heart attack are chest pain which may spread to the shoulders, neck or arms and shortness of breath. If you get these see a doctor straight away. Unexplained deaths have been reported but it is not proven that they were caused by promazine
- fever
- low body temperature
- low blood pressure. You may feel dizzy when standing up
- unusual movements, often of the mouth, lips, eyes and tongue. These movements can also include trembling and shaking of the hands and feet, twisting of the body, shuffling walk and stiffness of the arms and legs and unable to sit still
- eye changes such as blurred vision, clouding of the lens or purple colouring of the eye
- feeling confused, agitated or over-excited
- eye changes such as pain in the eye, blurred vision or loss of vision, seeing halos around lights, clouding of the lens or purple colouring of the eye.

Tell your doctor if you get any of these side effects:

- unable to sleep, feeling sleepy, drowsy or dizzy
- dry mouth, blocked nose
- constipation, difficulty in passing water particularly if you have an enlarged prostate
- skin rash caused by medicine spilt on your skin, skin rashes, skin reaction to direct sunlight
- swelling of the breasts (particularly in men) and breast milk production
- sexual impotence
- headache, upset stomach
- light periods or absence of periods
- weight gain.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Promazine Syrup

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. Protect from light.
- Do not use this medicine after the expiry date which is stated on the label and carton (EXP: month, year). The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the appearance or smell of your medicine has changed.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Promazine Syrup contains

- The active substance is promazine hydrochloride.
- The other ingredients are propylene glycol (E1520), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), sucrose, liquid glucose, ascorbic acid (E330), lemon lime flavor, sodium hydroxide, nitrogen and purified water.

What Promazine Syrup looks like and contents of the pack

Promazine Syrup is a clear, colourless to orange-brown coloured syrup.

It is packed in a amber glass bottle with tamper evident child resistant cap containing 150 ml of syrup.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in 04/2022

