Contents

1.3.4
CONSULTATION WITH TARGET PATIENTS GROUPS

Name of medicinal product	**Promazine Hydrochloride 25 mg/5 ml and 50 mg/5 ml Oral Syrup**
Client	**Zydus Pharmaceuticals UK Limited** Sandretto Building, Cavalry Hill Industrial Park, Weedon, Northampton, NN7 4PP, United Kingdom
This Report was prepared by	
This report was reviewed by	
Data was recorded by	
Data was processed by	
Company's Address	

Promazine Hydrochloride 25 mg/5 ml and 50 mg/5 ml Oral Syrup
Promazine hydrochloride

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1. Basic Introduction

The evaluation of the study was performed in accordance with: "Guidance concerning consultations with target patient groups for the package leaflet" (May 2006), EFPIA "General Recommendations for Readability User Testing of Package Leaflets for Medicinal Products for Human Use Submitted or Approved under the European Centralized Procedure" (March 2003), Annex to the EFPIA document (March 2002), MHRA "Guidance on the user testing of Patient Information Leaflets" (July 2005), MHRA "Always Read The Leaflet: Getting the Best Information With Every Medicine" (July 2005), MHRA "Further Guidance On Designing Patient Information Leaflets And How To Achieve Success In User Testing" (March 2007) and "Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use" (Revision 1, 12 January 2009).

Test details and outcome are presented with the package leaflet that incorporates any changes resulting from the assessment.

For this readability report, the product name is written as "**Promazine Hydrochloride 25 mg/5 ml and 50 mg/5 ml Oral Syrup**" or "**Promazine Syrup**".

2. Information about Product

The name of your medicine is Promazine hydrochloride 25 mg/5 ml or 50 mg/5 ml Oral Syrup (referred to as Promazine Syrup in this leaflet). It contains promazine hydrochloride. This belongs to a group of medicines called phenothiazines.
Promazine can be used to calm your emotions, particularly if you feel restless and agitated.

3. Brief Summary of Readability Testing Process

The user testing of the Package Information Leaflet (later referred to as the PIL) for **Promazine Syrup** was conducted in United Kingdom, London between 10-Sept-2025 to 26-Sept-2025.

Twenty-four (24) participants were tested in total.

- Four (4) participants were tested during the preliminary round of testing.
- Ten (10) participants were tested in the 1st round.
- Ten (10) participants were tested in the 2nd round.

A protocol depicting the testing process is also available as **Appendix 5** within this report.

3.1 Aspects Investigated in the Test and Methodology Used

The type of test used for the readability testing of this PIL was an evaluation and problem-seeking test.

The developed questionnaire contained 18 questions specific to **Promazine Syrup** and 3 specifics to the format of the package leaflet. The questions addressed all the key safety issues and concerns of **Promazine Syrup**. In formulating the questions, the test administrator first identified all the key safety messages in the PIL and then designed questions around those issues that would ensure a patient's comprehension and ability to act upon. For **Promazine Syrup**, the following key safety messages were addressed:

Key Safety Issue	Questions that addressed the Key Safety Issue
What **Promazine Syrup** is and what it is used for	**Question # 2** What information does the leaflet provide regarding the intended use of this medication?
Reasons not to take **Promazine Syrup**	**Question # 4** Suppose you have phaeochromocytoma and your doctor prescribed you **Promazine Syrup**. In such case, what does the leaflet advise.
Warnings and precautions related to **Promazine Syrup**	**Question # 15** Imagine your wife has Parkinson's Disease and her doctor prescribed **Promazine Syrup.** What does the leaflet advise or warn? **Question # 16** Suppose your father has kidney problems and his doctor prescribed **Promazine Syrup**. What does the leaflet advise or warn?
Promazine Syrup and it's ingredient	**Question # 18** Is there any information in this leaflet about the ingredients?
Other medicines and **Promazine Syrup**	**Question # 6** Imagine you are taking cimetidine to treat stomach problems. Your new doctor prescribes **Promazine Syrup**. What does the leaflet advise? **Question #10** Suppose your father is suffering from AIDS and taking ritonavir alongside **Promazine Syrup**. In this case, what does the leaflet advise?
Discontinuation of **Promazine Syrup**	**Question # 3** Does this leaflet provide any advice in case if you stop taking **Promazine Syrup** without talking with your doctor?
Issues concerning **Promazine Syrup** related to Pregnancy, breastfeeding and fertility	**Question # 1** Imagine you are pregnant; meanwhile, you are also taking **Promazine Syrup**. What does the leaflet advise in this condition?

Driving and using machines while taking **Promazine Syrup**	**Question # 14** What does the leaflet advice regarding driving and using machines while taking **Promazine Syrup**?
Promazine Syrup with alcohol	**Question # 8** Your brother is alcohol addictive, doctor prescribed him this medication. What does the leaflet say about this?
How to take **Promazine Syrup**	**Question #17** Does this leaflet give any guidance on how to take **Promazine Syrup**?
What if taken/given extra dose of **Promazine Syrup**	**Question #7** Does the leaflet provide any guidance on what to do if you take more than the suggested dose of medication?
What if you forgot dose of **Promazine Syrup**	**Question # 12** You forgot to take afternoon dose of **Promazine Syrup**. Does the leaflet give any information on it?
Storage of medicine	**Question # 11** What does the leaflet say about the storage, expiry, and disposal of **Promazine Syrup**?
Use of **Promazine Syrup in children and adolescents**	**Question # 13** Does this medication guide provide any details about use of this medication in children and adolescents?
Possible side effects of **Promazine Syrup**	**Question # 5** You are having yellowing of skin and whites of your eyes after starting treatment with **Promazine Syrup**. Does this leaflet give any information about these side effects? **Question # 9** You are unable to sleep with constipation and dry mouth after you started treatment with **Promazine Syrup**. Does the leaflet say something about this side effect?
Feedback Three additional questions that actively solicited positive and negative feedback from the participants about the user friendliness of the PIL were also included in the questionnaire. These comments have been recorded in Appendix 7 – Free Oral Opinion:	**Question #19** What are the good points of this leaflet? **Question #20** What are the bad points of this leaflet? **Question #21** On a scale of 1 to 5 how you would rate this leaflet if 1 is very easy and 5 is very difficult?

Promazine Hydrochloride 25 mg/5 ml and 50 mg/5 ml Oral Syrup
Promazine hydrochloride

The test was conducted through one-to-one structured interviews with a Test Administrator. The testing method included 24 participants and it was done in 3 stages:

- The initial testing involved 4 readily available participants. The main purpose being to identify any major problems with the PIL or the questionnaire.
- The 1st round of testing involved the interviewing of 10 participants.
- The 2nd round of testing involved the interviewing of an additional 10 participants.

The technical readability, comprehensibility of the text, traceability of information and the applicability were investigated in the test by the following methods:

1. General questions were used to investigate the technical readability and the traceability of the information for the following:

- Can you tell me what this medicine is used for?
- Can you tell me the recommended daily dose of this medicine?
- Can you tell me any main side effects of this product?
- Can you tell me if you take this medicine more or forgot to take the medicine?

2. Applicability questions were used to investigate the technical readability, traceability of the information, comprehensibility of the text and the applicability of the information for the following:

Question # 1

Imagine you are pregnant; meanwhile, you are also taking **Promazine Syrup**. What does the leaflet advise in this condition?

Question # 2

What information does the leaflet provide regarding the intended use of this medication?

Question # 3

Does this leaflet provide any advice in case if you stop taking **Promazine Syrup** without talking with your doctor?

Question # 4

Suppose you have phaeochromocytoma and your doctor prescribed you **Promazine Syrup**. In such case, what does the leaflet advise?

Question # 5

You are having yellowing of skin and whites of your eyes after starting treatment with **Promazine Syrup**. Does this leaflet give any information about these side effects?

Question # 6

Imagine you are taking cimetidine to treat stomach problems. Your new doctor prescribes **Promazine Syrup**. What does the leaflet advise?

Question #7

Does the leaflet provide any guidance on what to do if you take more than the suggested dose of medication?

Question # 8

Your brother is alcohol addictive, doctor prescribed him this medication. What does the leaflet say about this?

Question # 9

You are unable to sleep with constipation and dry mouth after you started treatment with **Promazine Syrup**. Does the leaflet say something about this side effect?

Question #10

Suppose your father is suffering from AIDS and taking ritonavir alongside **Promazine Syrup**. In this case, what does the leaflet advise?

Question # 11

What does the leaflet say about the storage, expiry, and disposal of **Promazine Syrup**?

Question # 12

You forgot to take afternoon dose of **Promazine Syrup**. Does the leaflet give any information on it?

Question # 13

Does this medication guide provide any details about use of this medication in children and adolescents?

Question # 14

What does the leaflet advice regarding driving and using machines while taking **Promazine Syrup**?

Question # 15

Imagine your wife has Parkinson's Disease and her doctor prescribed **Promazine Syrup.** What does the leaflet advise or warn?

Question # 16

Suppose your father has kidney problems and his doctor prescribed **Promazine Syrup**. What does the leaflet advise or warn?

Question #17

Does this leaflet give any guidance on how to take **Promazine Syrup**?

Question # 18

Is there any information in this leaflet about the ingredients?

Question #19

What are the good points of this leaflet?

Question #20

What are the bad points of this leaflet?

Question #21

On a scale of 1 to 5 how you would rate this leaflet if 1 is very easy and 5 is very difficult?

Safety issues specific to **Promazine Syrup** were addressed using questions that used imaginary situations to verify that the participant comprehended and was able to apply the information to make the correct decision.
Quantitative and qualitative data were recorded and assessed by the interviewer to determine if the participant traced the correct section and answered the question correctly. The interviewer used criteria explained in instructions for the interviewer (**Appendix 3**).

For qualitative results, if the subject found the information and/or answered the question correctly but demonstrated difficulty in locating or understanding it, this is interpreted as a negative result for that question and affects in the Quantitative Results section. This is concluded directly by the interviewer and marked as a fail in the Answer Sheet.

Additionally, if more than 50% of participants in each round demonstrate they can only locate and understand the information with a moderate effort, suggestions for changes might be offered and, if necessary, areas of the PIL to which the data pertain can be revised to improve the PIL.

A satisfactory test outcome is when, for each question, 90% of all participants are able to find the information requested within the PIL and 90% can show that they understand and can act upon it. However, since the overall assessment of the PIL is very important, a fail on a question is not necessarily a fail of the test, unless it concerns a key message within the PIL. In such a case, any failed question is reported and discussed in this document.

The participant responses to questions 19, 20 and 21 are discussed if the same or similar comment was made by at least 30% of the participants. These comments can be found on the answer sheet as Appendix 7 to this report. However, they are not enacted and are recorded only as a matter of reference, if less than 30% of participants in one round of testing addressed the same issue. Participants are also asked to rate the PIL's overall accessibility on a scale of 1 to 5, with 1 being easy to understand, 5 difficult.

3.2 Demographics

Participants were recruited by placing notice boards in a local library or community center or any specific public place. The participants were informed that they would be participating in an important test about a patient information leaflet and were compensated for their time appropriately. Considering the current situation of Corona pandemic, all measures of precautions were taken care while conducting this study and only single participant as one time was enrolled with assurance of having no symptoms of Covid or any other infection was enrolled. All government norms were followed during testing.

The medicine given to adults only. Considering this, the target groups, who were considered to be potential users of Promazine Syrup are adults, from age of 18 to 60 years and hence accordingly candidates were selected considering the fact that they are the more frequent users of this medicine.

In the "recruitment" process of participants, the interviewer will always ask whether the participant has ever been involved in user testing in the past. If so, they are disqualified in ever taking part in a user test performed earlier. The participants will also be asked if they are or did work in the following industries:

- Pharmaceuticals
- Medical
- Market research
- Media (newspapers, magazines, advertising agencies or publishing companies)

If so, they were automatically disqualified due to possible understanding of the testing methodology, direct experience with PILs and/or having an above average knowledge of the language.

The genders of the participants selected for this test were:

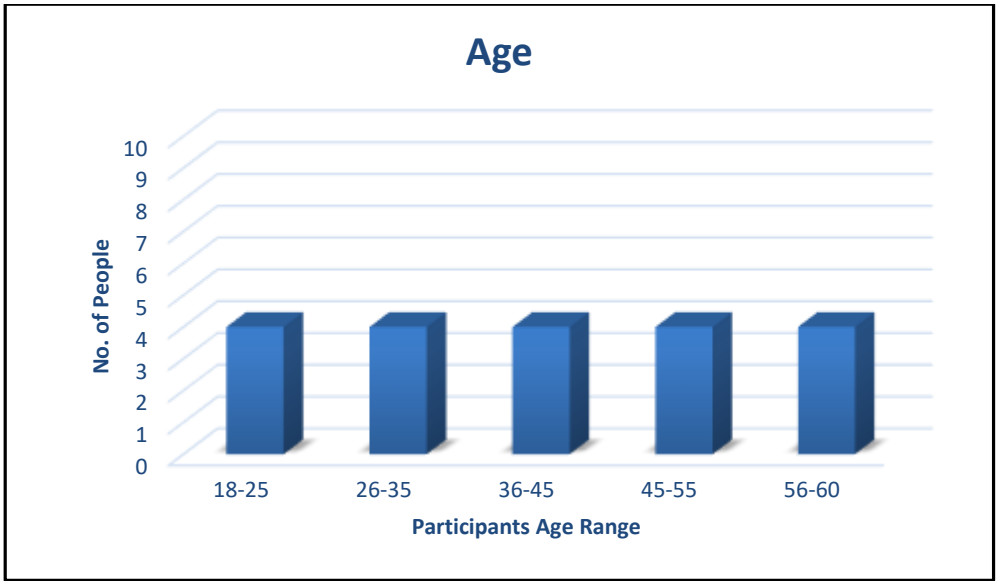
- 50% male and 50% female

The education levels of the participants were:

- 20% GSCE
- 40% A-Level
- 40% Vocational School

The age groups of the participants for the 1st and 2nd round of testing are:

- 20% between 18-25 years of age
- 20% between 26-35 years of age
- 20% between 36-45 years of age
- 20% between 46-55 years of age
- 20% 56 years of age or older



3.3 Detailed Testing Procedure

1. Initial review of the PIL. The PIL was reviewed by an experienced test administrator.
2. A questionnaire was prepared with 18 questions addressing the issues stated above.
3. A pilot round of testing was performed on 4 readily available participants.
4. No suggestions for changes were given based on preliminary testing.
5. Recruitment, selection and scheduling of participants. 20 participants were selected to meet the wide range of demographics preferred for this test.
6. The 1st round of testing was performed over 3 days.
7. The data from the 1st round of testing was processed and analyzed.
8. No suggestions for changes were given based on the first round of testing.
9. The 2nd round of testing was performed in 5 days.
10. Data for the 2nd round of testing was processed and analyzed.
11. No suggestions for changes were given based on the second round of testing.
12. The final report was created.

4. Timeline

The timeline for readability user testing is attached as **Appendix 1**.

5. Questionnaire

Questionnaire is attached as **Appendix 2**.
Instructions for the interviewer is attached as **Appendix 3**.

6. Package Leaflet

Before testing

The leaflet was assessed by an experienced project manager and finalized for readability testing.

The technical specifications of the PIL:

Main text font	Arial 9 pt.
Heading font	Arial 14 pt.
Paper dimensions	490 x 160 mm
Format	Will remain same
Color	Black

After testing

Based on quantitative and qualitative results from testing, no edits were suggested to PIL.
The package leaflet used for readability testing is attached as **Appendix 4**.

7. Results

Preliminary round of testing

The PIL was initially tested with 4 participants. The participants were informed that they are participating in the test of the leaflet. The leaflet was used to answer the questions. The interviewer observed how and where participants found the information on the leaflet and how they would act on it. All participants were asked the same questions, as the interviewer was using a questionnaire. No notes were taken while the participants were answering the questions.

There were no changes made to the PIL based on preliminary testing.

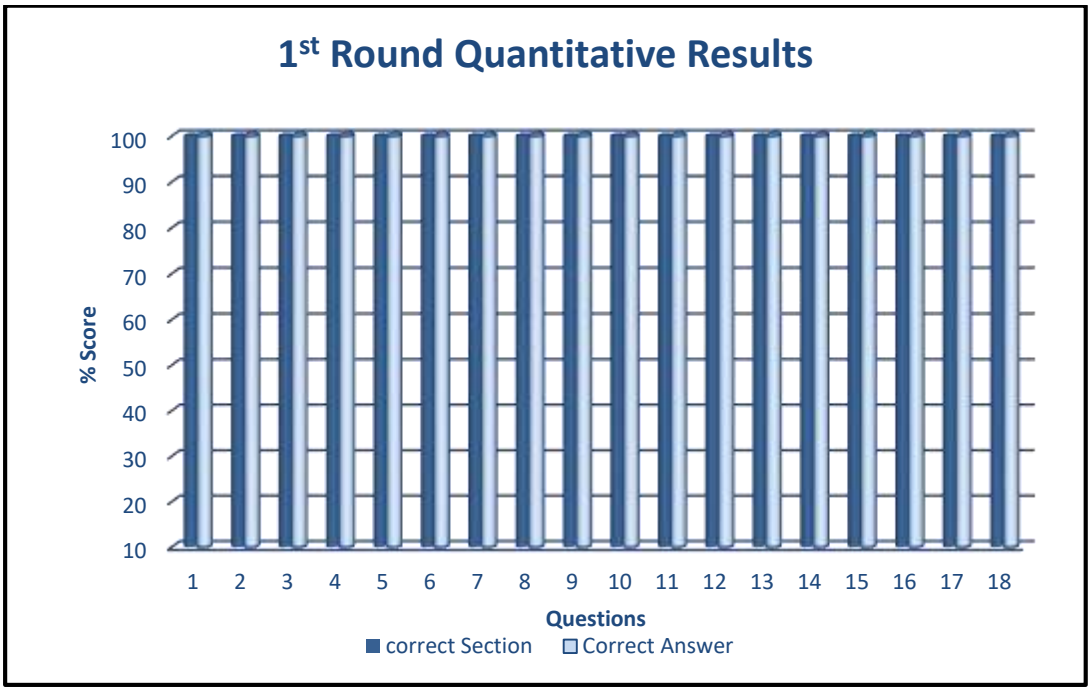
7.1 First Round of Testing

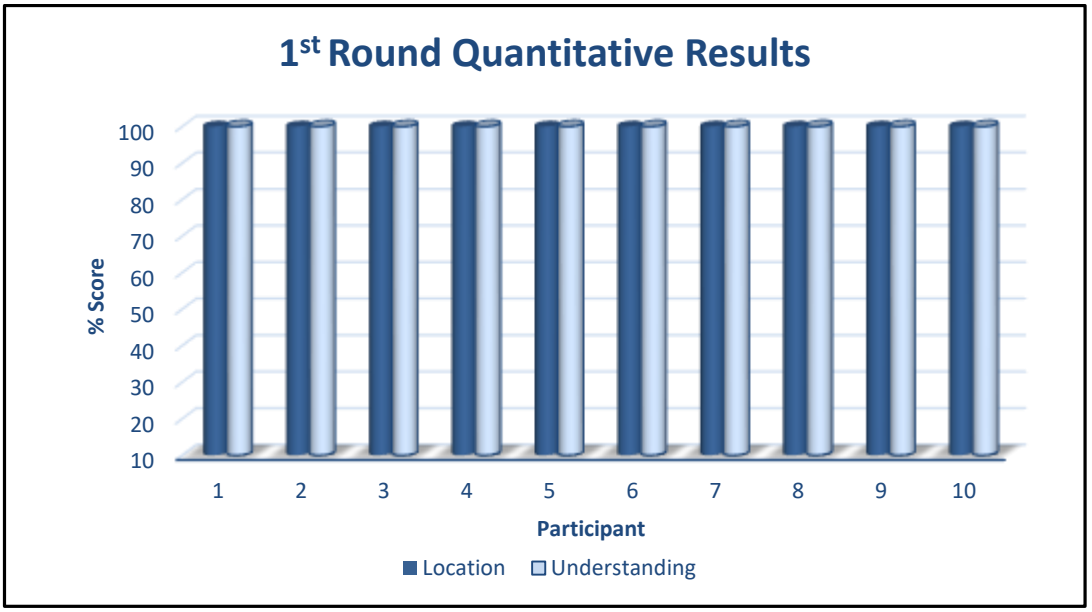
7.1.1 First Round Quantitative Results

Quantitative Results by Question 1st Round

The results of the 1st round of testing are shown below. The graph below details scores to each question.

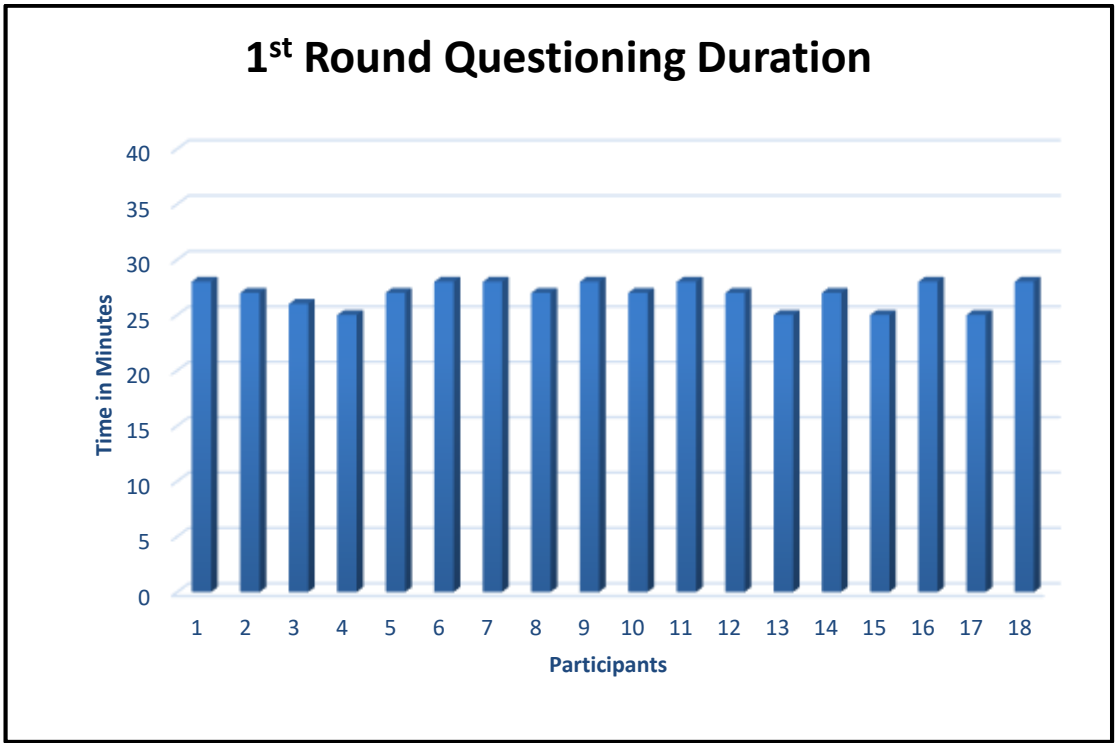
A satisfactory test outcome is when, for each question, 90% of all participants are able to find the information requested within the PIL, and 90% of all participants can show that they understand and can act upon it. The data show all 18 questions met these passing criteria.





Interview Duration

The number of minutes it took each participant to answer all of the questions in Round 1.



7.1.2 First Round Qualitative Results

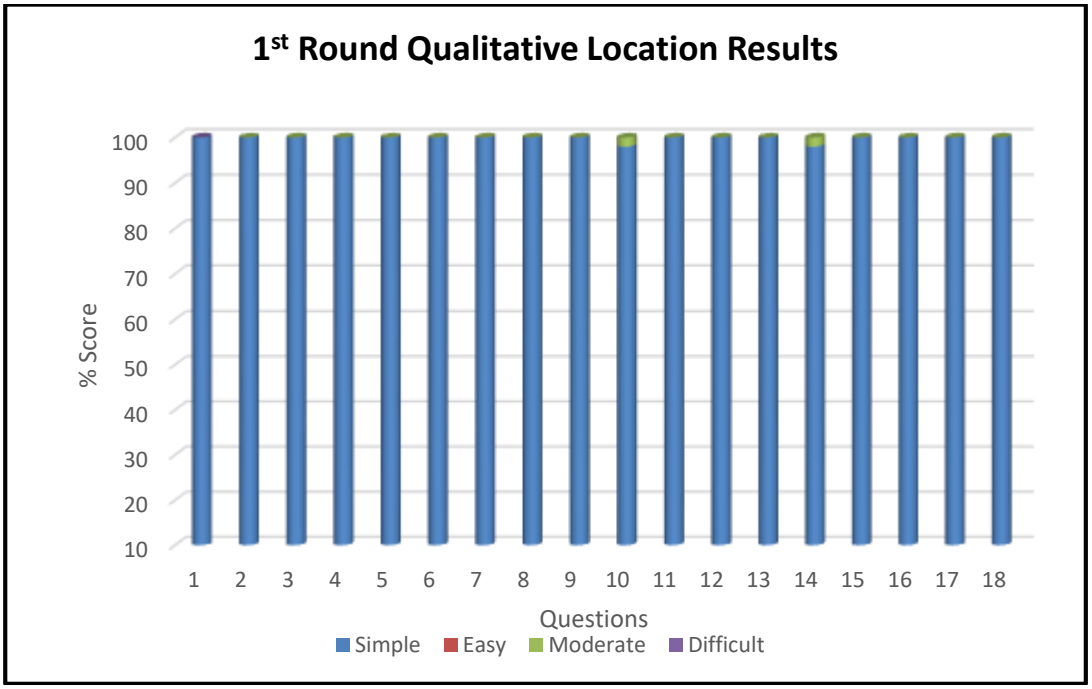
Qualitative Results by Question 1st Round

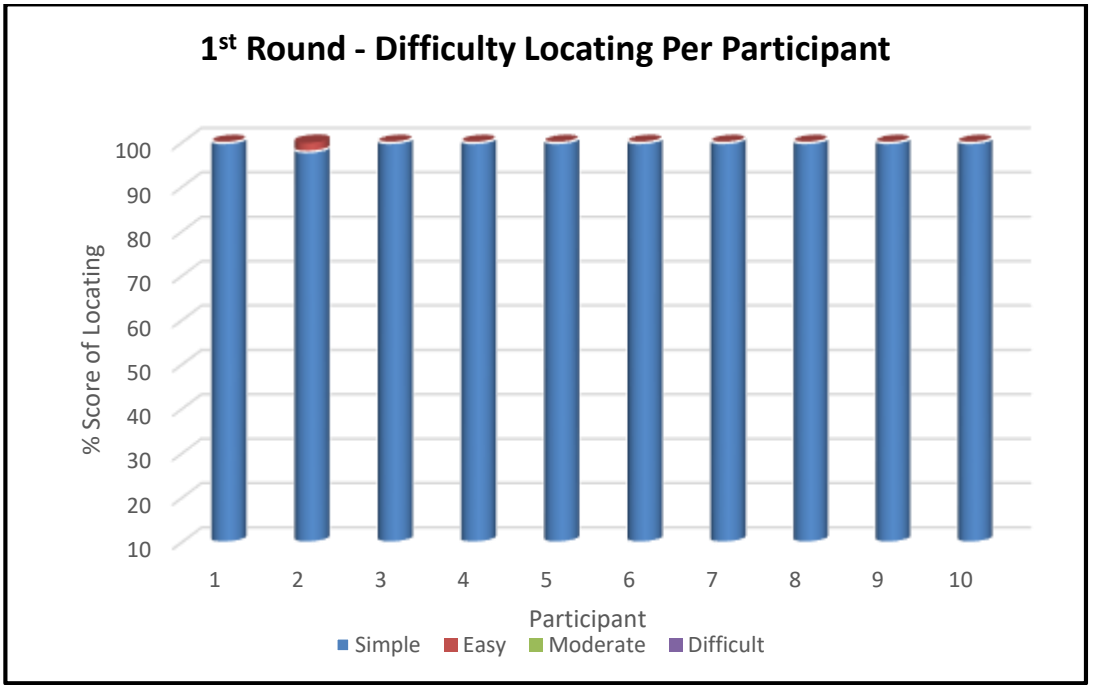
The qualitative results are detailed below in two separate graphs, one measuring the participants' ability to locate the information, the other measuring the participant's ability to understand the information addressed in each question.

The interviewer used criteria explained in instructions for the interviewer (Appendix 3). The Difficulty Locating graph depicts the level of difficulty a participant exhibited finding the correct section while the Difficulty Understanding graph depicts the level of difficulty a participant exhibited understanding/acting upon the located information. The difficulty is graded using the following scale: 0 = simple, 1 = easy, 2 = moderate and 3 = difficult.

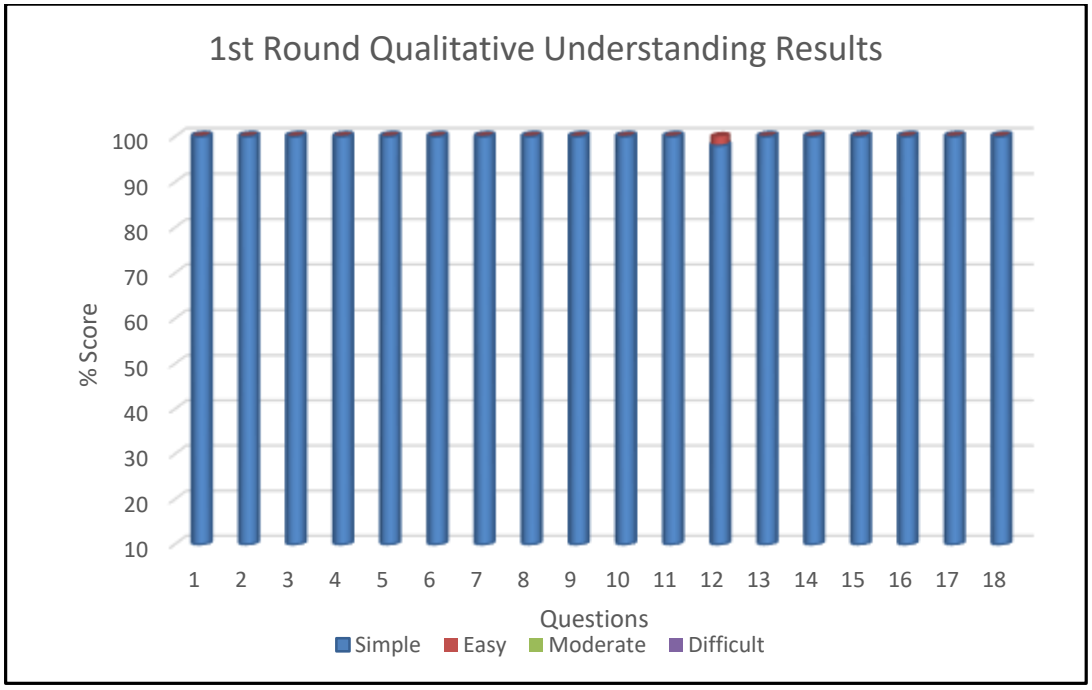
If the subject found the information and/or answered the question correctly but demonstrated difficulty (scored as "Difficult" in the graph below or as "3" in the Answer Sheets) in locating or understanding it, this is interpreted as a negative result for that question and affects the Quantitative Results section. This is concluded directly by the interviewer and marked as a fail in the Answer Sheet.

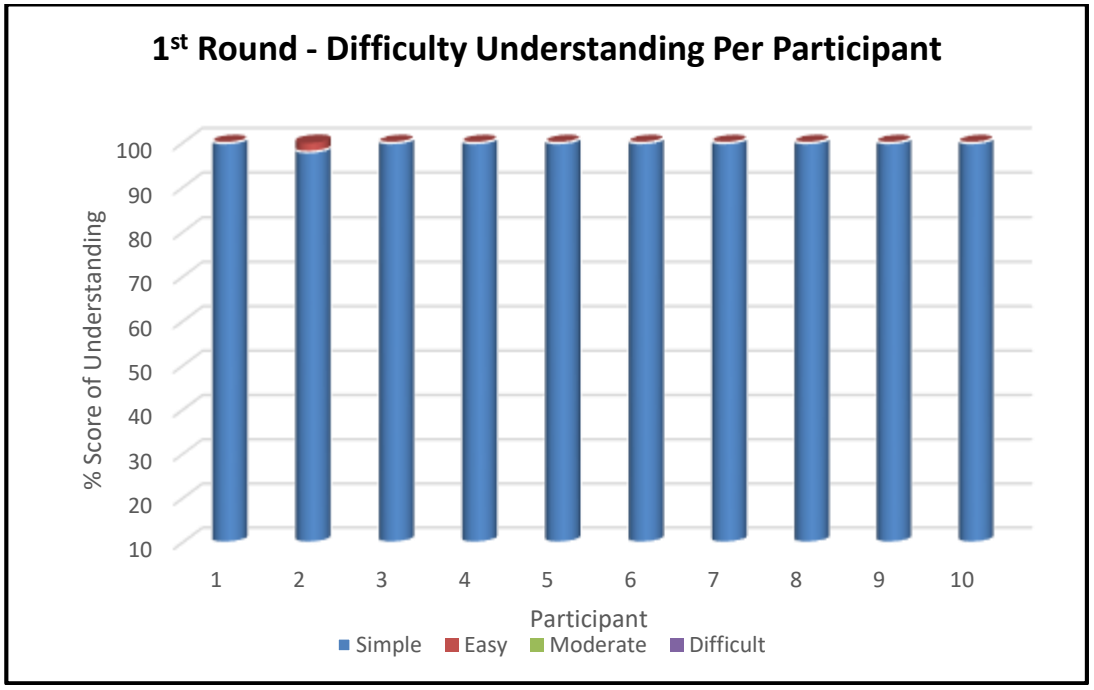
Location Results





Understanding Results





First Round Free oral opinion

Positive and negative feedback are actively solicited from each subject at the end of the test. If 3 or more subjects express the same negative opinion on a general or particular aspect of the leaflet then this is mentioned here. Also, if a single subject points out an issue that is deemed significant then this is also recorded.

Participant comments
All participants from Round 1 gave positive feedback on the leaflet. They mentioned that it was clear and easy to read and also noted that it is precise and informative. Participants also appreciated that the leaflet is well laid out and was easy for them to find information. No negative comments were received.

Summary
Based on quantitative and qualitative results from the first round, no changes were made to the PIL for the second round of testing.

Since there were no other problems during testing, the participant opinions (see Appendix 7) were not enacted but were recorded only as a matter of reference.

7.2 Second Round Results

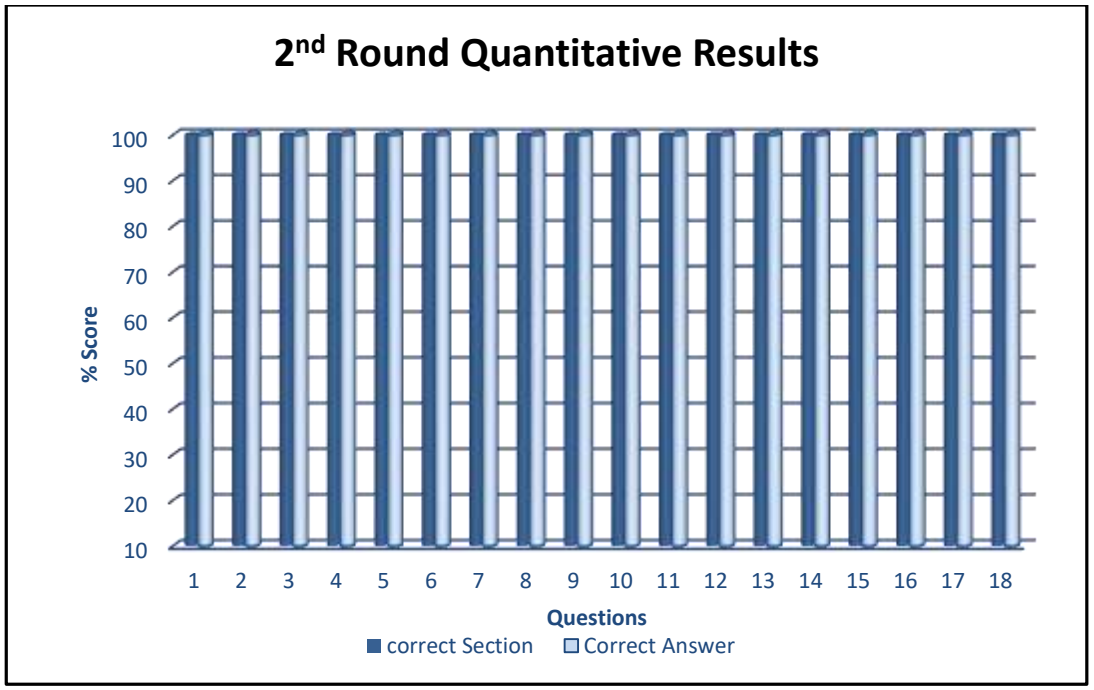
7.2.1 Second Round Quantitative Results

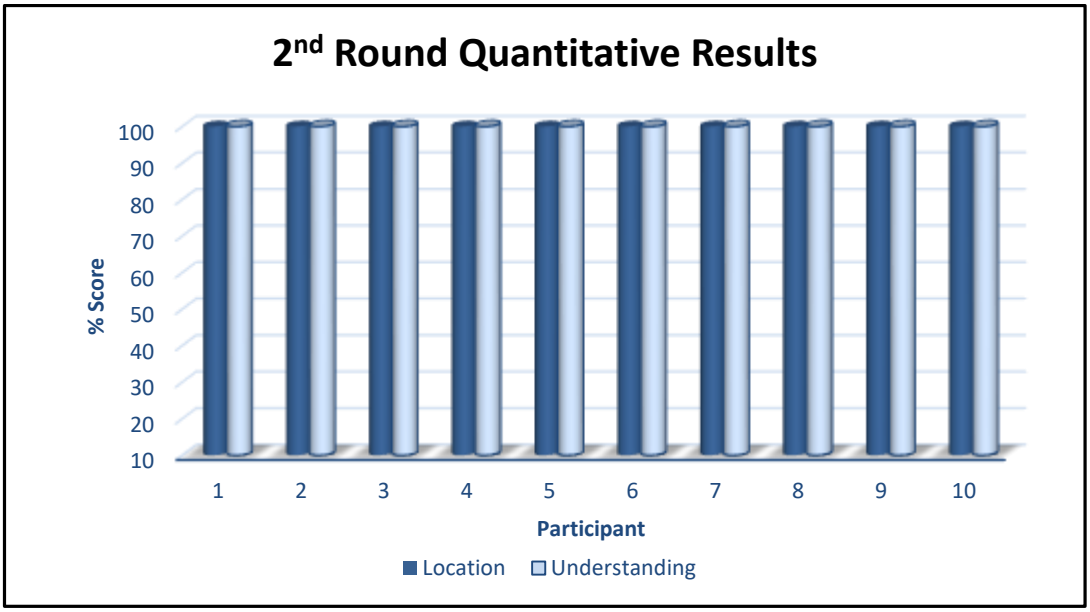
Quantitative Results by Question 2nd Round

The results of the 2nd round of testing are shown below. The graph below details scores to each question.

A satisfactory test outcome is when, for each question, 90% of all participants are able to find the information requested within the PIL, and 90% of all participants can show that they understand and can act upon it.

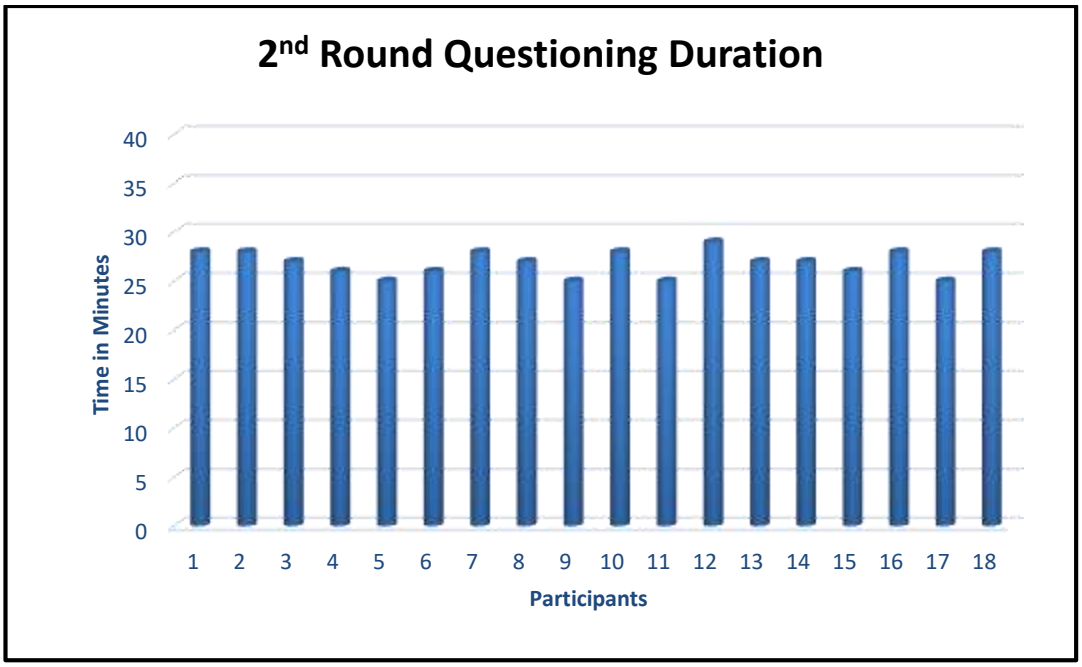
The data show all 18 questions met these passing criteria.





Interview Duration

Number of minutes it took each participant to answer all of the questions in Round 2.



7.2.2 Second Round Qualitative Results

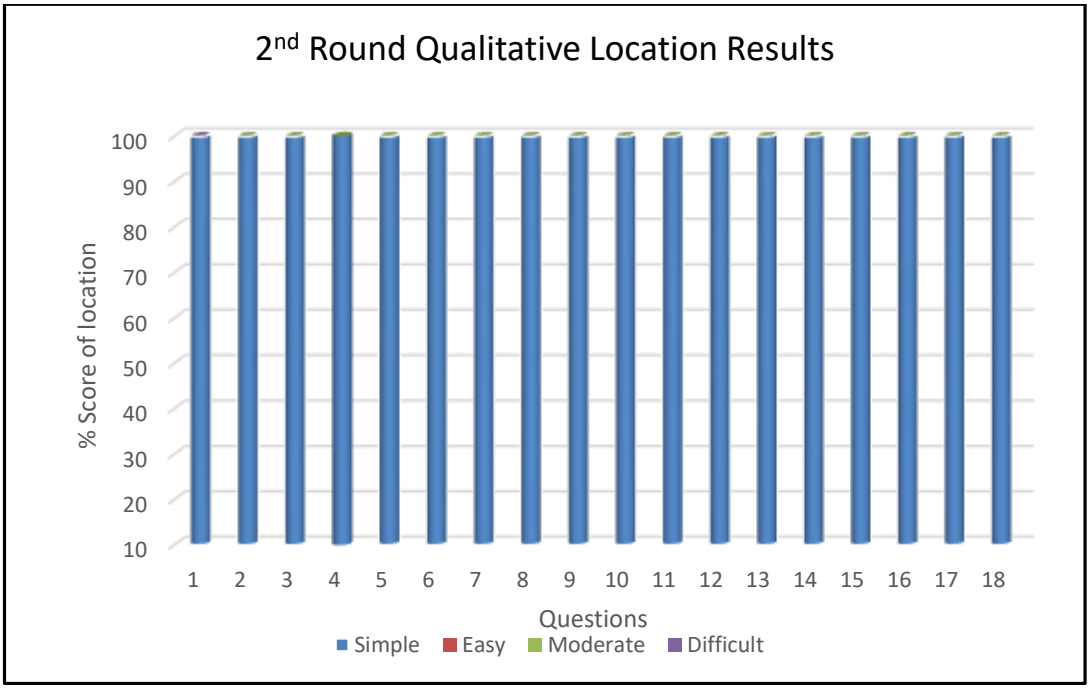
Qualitative Results by Question 2nd Round

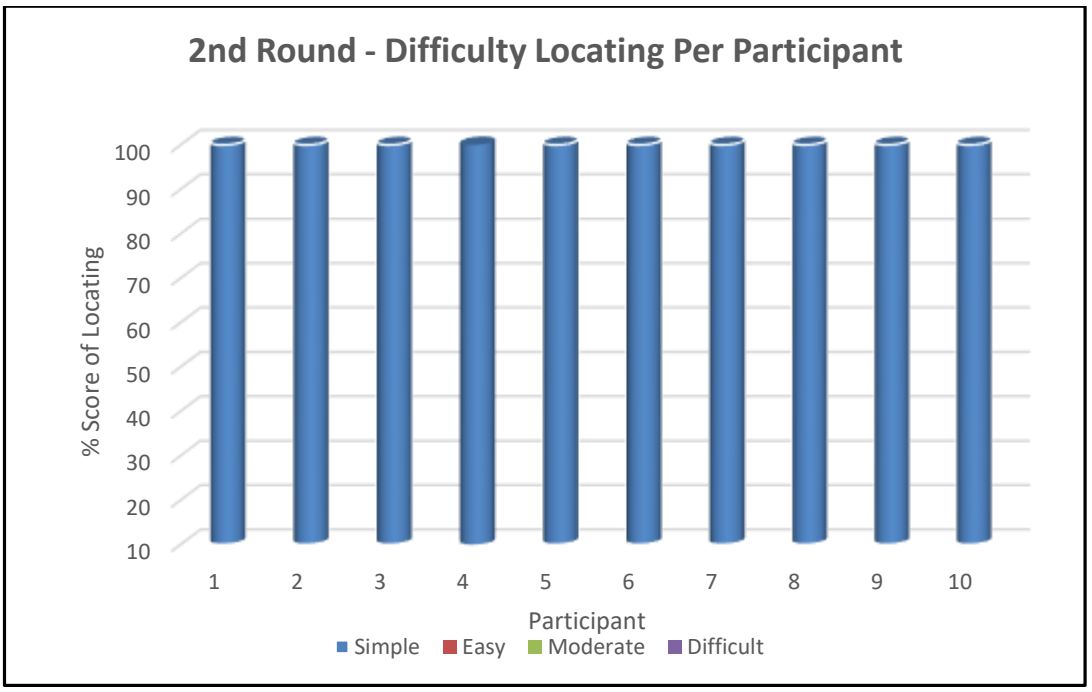
The qualitative results are detailed below in two separate graphs, one measuring the participants' ability to locate the information, the other measuring the participants' ability to understand the information addressed in each question.

The interviewer used criteria explained in instructions for the interviewer (Appendix 3). The Difficulty Locating graph depicts the level of difficulty a participant exhibited finding the correct section while the Difficulty Understanding graph depicts the level of difficulty a participant exhibited understanding/acting upon the located information. The difficulty is graded using the following scale: 0 = simple, 1 = easy, 2 = moderate and 3 = difficult.

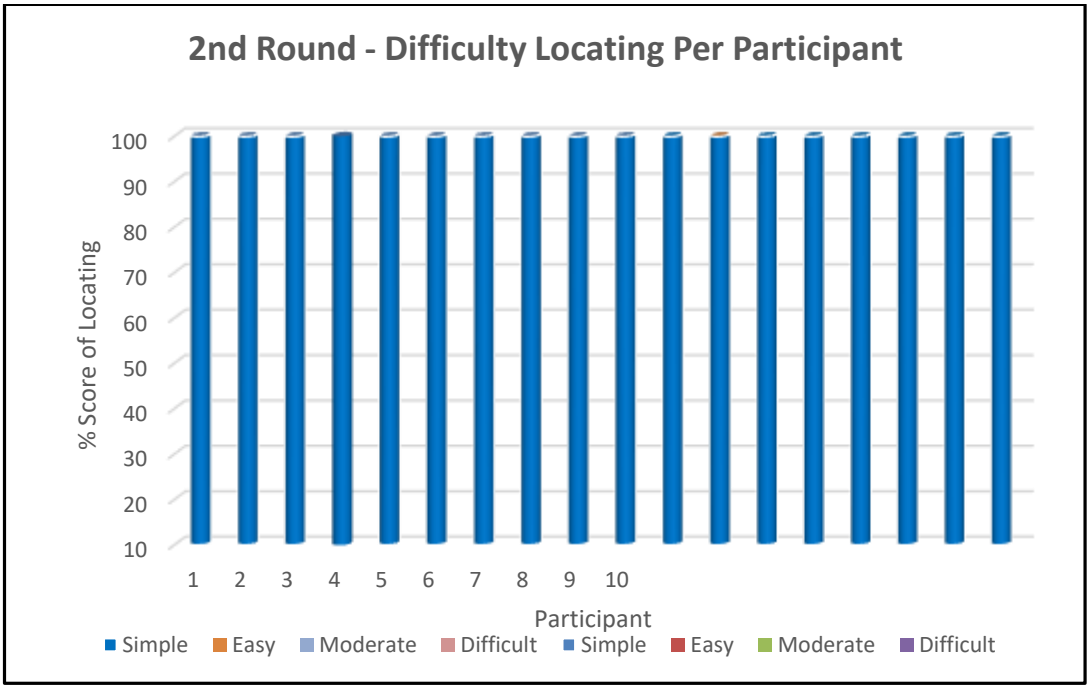
If the subject found the information and/or answered the question correctly but demonstrated difficulty (scored as "Difficult" in the graph below or as "3" in the Answer Sheets) in locating or understanding it, this is interpreted as a negative result for that question and affects the Quantitative Results section. This is concluded directly by the interviewer and marked as a fail in the Answer Sheet.

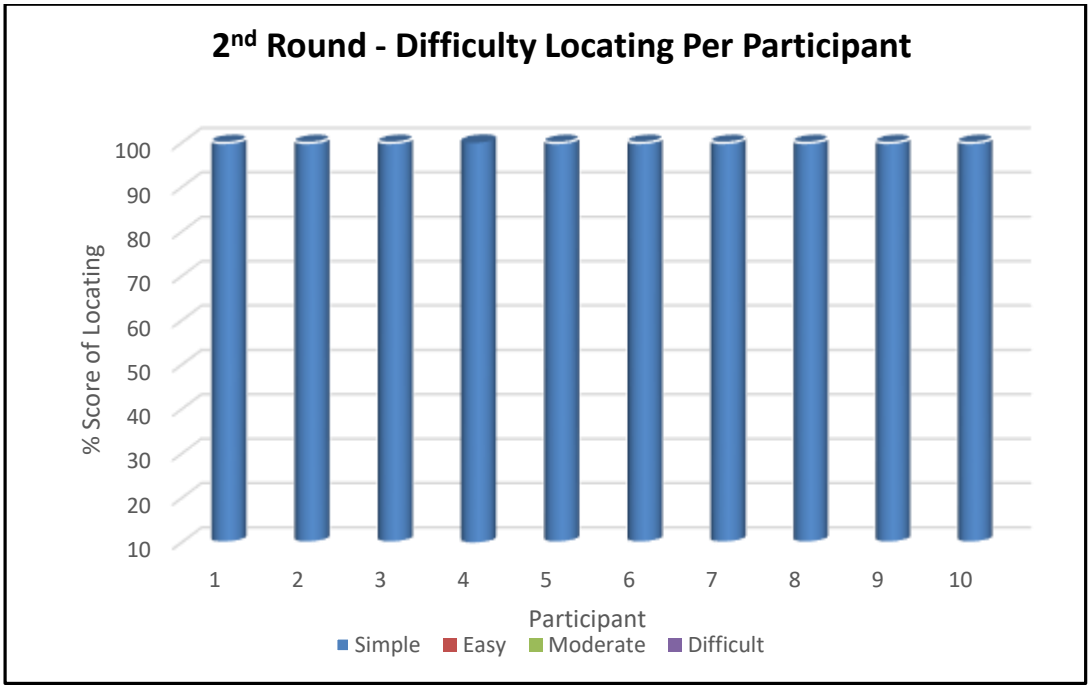
Location Results





Understanding Results





Second Round Free oral opinion

Positive and negative feedback are actively solicited from each subject at the end of the test. If 3 or more subjects express the same negative opinion on a general or particular aspect of the leaflet then this is mentioned here. Also, if a single subject points out an issue that is deemed significant then this is also recorded.

Participant comments
Overall, participants offered positive feedback on the leaflet. They noted that it is very informative and concise, and the text is located in the relevant sections. They also appreciated the layout and use of headings, saying this made the leaflet easy to read.

Summary
Based on quantitative and qualitative results from the second round, no changes were made to the PIL after testing.

Since there were no other problems during testing, the participant opinions (see Appendix 7) were not enacted but were recorded only as a matter of reference.

8. Summary and Discussion of the Results

The package leaflet for **Promazine Syrup** has been user tested and achieved a satisfactory result according to the criteria stated in the report.

Accurate answers to the specific oral questions were the base of the assessment. A satisfactory test outcome is when, for each question, more than 90% of the subjects of the interviews were able to find the information within the PIL, and more than 90% could show that they understood and could act upon it.

Participant's comments:

Round 1
All participants from Round 1 gave positive feedback on the leaflet. They mentioned that it was clear and easy to read and also noted that it is precise and informative. Participants also appreciated that the leaflet is well laid out and was easy for them to find information. No negative comments were received.

Round 2
Overall, participants offered positive feedback on the leaflet. They noted that it is very informative and concise, and the text is located in the relevant sections. They also appreciated the layout and use of headings, saying this made the leaflet easy to read.

9. Conclusion

The results of this test indicate that the PIL is well structured and organized, easy to understand and written in a comprehensible manner. The test shows that the leaflet is readable and patients/users are able to act upon the information that it contains. This report also meets the legal requirements for Art. 59(3) of Directive 2001/83/EC (as amended).

Neocubes also confirms the report conforms to the study design, principles and success criteria featured in the European Commission's document "Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use (Revision 1, 12 January 2009)."

Based on the above-mentioned facts the package leaflet can be qualified as ACCEPTABLE.

[redacted]

10. Appendices

Appendix 1 Timeline of testing

Date	Action
Sept 10, 2025	The PIL text was received and reviewed by Project Manager
Sept 11, 2025	A questionnaire was created of 18 questions addressing the key safety issues.
Sept 13, 2025	The selection and scheduling of participants commenced. The initial testing of the PIL was performed with 4 participants.
Sept 14, 2025 to Sept 17, 2025	1st round of testing was performed.
Sept 18, 2025	The data from the 1st round of testing was processed and analysed. The results were deemed acceptable and testing progressed to the second round.
Sept 19, 2025 to Sept 22, 2025	2nd round of testing was performed.
Sept 23, 2025	The data from the 2nd round of testing was processed and analysed.
Sept 24, 2025 to Sept 27, 2025	The readability testing report was finalized based on the results obtained during 1st and 2nd round for submission.

Appendix 2- Questionnaire

Hello, my name is [redacted] I'm here today on behalf of [redacted] to test a package insert. We are doing this to improve the visual presentation and quality of information that's presented in the package insert. After the interviewing process is over, we will take into consideration all the comments you have made regarding the patient insert to make it more user friendly for people who will potentially use this type of medicine.

Don't worry; we are not testing you, your knowledge, or your memory. This interview process is purely to test the information that's presented in this package information leaflet. It will also be very useful to know where and how you find the information and whether you can apply it to your daily life.

In order for us to cover all the sections in the patient leaflet, I will use an already designed questionnaire. Don't be disturbed, as I will be taking notes while you answer my questions as well so that we can conclude the readability testing outcome based on your feedback.

In order to prove that this interview has taken place, as well as to provide reference for later use, it will be voice recorded based on your agreement. Your name and any relevant personal details are not going to be on the tape recording though.

I hope I have explained why we are here and why we are doing this but if not, please let me know. Do you agree that you've had the necessary time to look over this insert as you would normally do so? Before we begin with the questionnaire, I have a few preliminary notes to take on your usual tendencies with regards to inserts like this:

- Can you please tell me whether you read the leaflets that come with medicine?
- Do you usually experience difficulties when reading information of such kind?

Let's begin.

Question # 1

Imagine you are pregnant; meanwhile, you are also taking **Promazine Syrup**. What does the leaflet advise in this condition?

Question # 2

What information does the leaflet provide regarding the intended use of this medication?

Question # 3

Does this leaflet provide any advice in case if you stop taking **Promazine Syrup** without talking with your doctor?

Question # 4

Suppose you have phaeochromocytoma and your doctor prescribed you **Promazine Syrup**. In such case, what does the leaflet advise.

Question # 5

You are having yellowing of skin and whites of your eyes after starting treatment with **Promazine Syrup**. Does this leaflet give any information about these side effects?

Question # 6

Imagine you are taking cimetidine to treat stomach problems. Your new doctor prescribes **Promazine Syrup**. What does the leaflet advise?

Question #7

Does the leaflet provide any guidance on what to do if you take more than the suggested dose of medication?

Question # 8

Your brother is alcohol addictive, doctor prescribed him this medication. What does the leaflet say about this?

Question # 9

You are unable to sleep with constipation and dry mouth after you started treatment with **Promazine Syrup**. Does the leaflet say something about this side effect?

Question #10

Suppose your father is suffering from AIDS and taking ritonavir alongside **Promazine Syrup**. In this case, what does the leaflet advise?

Question # 11

What does the leaflet say about the storage, expiry, and disposal of **Promazine Syrup**?

Question # 12

You forgot to take afternoon dose of **Promazine Syrup**. Does the leaflet give any information on it?

Question # 13

Does this medication guide provide any details about use of this medication in children and adolescents?

Question # 14

What does the leaflet advice regarding driving and using machines while taking **Promazine Syrup**?

Question # 15

Imagine your wife has Parkinson's Disease and her doctor prescribed **Promazine Syrup.** What does the leaflet advise or warn?

Question # 16

Suppose your father has kidney problems and his doctor prescribed **Promazine Syrup**. What does the leaflet advise or warn?

Question #17

Does this leaflet give any guidance on how to take **Promazine Syrup**?

Question # 18

Is there any information in this leaflet about the ingredients?

Question #19

What are the good points of this leaflet?

Question #20

What are the bad points of this leaflet?

Question #21

On a scale of 1 to 5 how you would rate this leaflet if 1 is very easy and 5 is very difficult?

Appendix 3 Interview Procedure & Guidance Notes

Instructions to the Interviewer
User Testing of Package Information Leaflets

Before the interview

1. Allow as much time as necessary for each interview. For example, elderly subjects might need more time to locate and read the necessary information in the patient leaflet. Schedule interviews at least 1 hour apart.
2. Interviews should be done with one subject at a time in a private, quiet location/room.
3. The interview location should be in a casual environment to put the participant at ease.
4. When scheduling interview participants, ask each participant if they have ever previously been involved in leaflet user testing. If the participant states that he/she has previously been involved, the participant is disqualified and cannot be involved in leaflet user testing.
5. Ensure that all equipment is ready for the interview (i.e. data collection sheets, voice recorder (if subject agrees to allow recording), pen for note taking).
6. Sometime, if a participant agrees, underlining the answer of particular question is also considered as record. The question will be written inside of the area where the answer is underlined.
7. It is also ensured that the health of all participants is good. None of the participants should have any sign of Covid.

Initial instructions for the participants:

1. Follow the format of the questionnaire.

    a. At the beginning of the interview explain the objective of the test and procedure.
    b. It is important to tell the participants they came to test the leaflet and make the information they see on the leaflet as clear as possible and easy to find for people who will take this medicine in the future.
    c. Explain to them we are testing the leaflet to make sure it is as user friendly as possible. Explain that this test has implications to help people in the future.
    d. Make sure participants understand they did not come to the interview to test their common sense or memory, but to test the leaflet. Ask them to use the leaflet to answer the questions. They can read or look through the PIL. They should consult the PIL throughout the testing.
    e. Tell them that we are interested in how and where they find the information on the leaflet and how they would act on it.
    f. Tell and remind people as necessary that our investigation into the package leaflet is not a memory test.
    g. Ask questions in random order relative to the order of information in the PIL.
    h. Allow participants to review the PIL as they normally would if they received a new medication. Offer examples of how some people review the PIL.

Measuring correct location

To ensure that the subject has located the correct section, containing the information relevant to the question, ask him/her to say in which section and where in that section the information is located. In some instances, the relevant information may be repeated in more than one location in the leaflet. In such cases it is sufficient if the subject locates one of these places.

Record where the participant found the information.

Measuring a correct answer and ensuring the participant has used the PIL to Answer

1. A correct answer is given when the participant demonstrates that he/she comprehends the information and demonstrates that he/she can act upon it.
2. To record an answer as correct, you must be sure the participant has demonstrated 3 criteria:
    a. He/she can give the correct answer.
    b. He/she can apply the information to the imaginary situation correctly.
    c. He/she can express the relevant information regarding this question in his/her own words (not simply read it out loud from the leaflet).
3. You must be sure the participant answered correctly to record it as correct. If in doubt, use follow up questions to ensure the participant understands.
4. Asking the participant to point out the section used to answer the questions ensures that the answer wasn't given from memory or common sense, which would invalidate the results of the test.

Conducting the test (interview)

1. Ask the questions from the questionnaire in the order they are written.
2. Paraphrase questions if needed to ensure the participant comprehends the question.
3. Ensure the participant uses the leaflet to answer the questions, not common sense or memory. To do this, always ask after each question and answer where the information was located on the leaflet. Record whether or not the participant located the correct section.
4. Record the method used by the participant to locate the information on the PIL. (i.e. scanned the leaflet, used the table of contents, went directly to the section).
5. Record the participant's response. Ask the participant not to read the information from the PIL, but to use his/her own words when possible.
6. If the participant hesitates to answer, solicit information by asking follow up questions. Allow the participant plenty of time to locate the section. Remind them there is no time limit. Record the ease or difficulty the participant demonstrates.
7. Under no circumstances it is acceptable to prompt or aid the participant.
8. Record a qualitative measure of the difficulty the subject must first locate the information and then separately to understand/act upon the located information.
9. In order to gauge the **qualitative** response, the following physical factors should be taken into account:
    a. time taken for the participant to respond,
    Although you will be putting the subjects at ease at the start of the interview by telling them "Take your time. There is no rush. There is no time limit for this interview", the

questionnaire is designed so that the slowest subjects should take less than 45 minutes to complete the whole interview.

You also need to monitor response times on individual questions. In general location or understanding should take no more than 2 minutes for each question. However, you need to adapt to the subject and circumstances. If a subject is distracted by an unusual noise, coughing attack or other external factor then that must be taken into account. Also, if the subject is young and has demonstrated great speed on earlier questions, then a long response time on a later question should be noted earlier than the 2-minute deadline.

b. if the participant repeats the question themselves,
c. if the participant asks questions,
d. if the participant turns over the leaflet and/or scans the leaflet without direction,
e. if the participant reads the same section more than once,
f. if the participant hesitates when reporting a location or explaining the meaning of a response,
g. general impressions that the participant cannot locate or is having difficulty locating the information or understanding it once located.

10. When noticing any of the above actions, grade the qualitative response as either: simple (0), easy (1), moderate (2) or difficult (3) using the following definitions where applicable (although the final decision needs to be made taking in various other factors of the participant [i.e. age, eye sight, etc.])
    a. Simple: the participant demonstrates none of the criteria listed above for a correct answer or for a correct location.
    b. Easy: the participant demonstrates no more than one of the physical responses listed above.
    c. Moderate: the participant demonstrates no more than three of the physical responses listed above.
    d. Difficult: the participant demonstrates more than three of the physical responses listed above.
11. If the participant fails to locate and/or understand the information, mark it as difficult.
12. If the participant finds the information and/or answers the question correctly but demonstrated difficulty in locating or understanding it, mark it as a fail.
13. Solicit positive and negative feedback. Record comments.

Appendix 4 Original Package Leaflet

Please refer the annexure - **Original Package Leaflet.**

Appendix 5 Protocol

PROTOCOL
User Readability Testing for the Package Information Leaflet (PIL) for

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

Name of medicinal product	**Promazine Hydrochloride 25 mg/5 ml and 50 mg/5 ml Oral Syrup**
Client	**Zydus Pharmaceuticals UK Limited**
This Protocol was prepared by	[redacted]
This Protocol was reviewed by	

Guidance Summary

The name of your medicine is Promazine hydrochloride 25 mg/5 ml or 50 mg/5 ml Oral Syrup (referred to as Promazine Syrup in this leaflet). It contains promazine hydrochloride. This belongs to a group of medicines called phenothiazines.
Promazine can be used to calm your emotions, particularly if you feel restless and agitated.

Test design:

To ensure most critical information is easily located, understood and that instructions can be followed correctly, face to face, structured interviews with the questionnaire based on prioritized data from the PIL will be conducted. Interviews will be divided into 3 stages:

- Preliminary test during which major changes to the leaflet can be identified
- 1st round will involve the initial testing on 10 participants
- 2nd round will involve testing on 10 participants

Creation of Questionnaire:

The questionnaire will be developed to include 18 questions specific to the product and 3 specifics to the format of the leaflet. The questions will address key safety issues and concerns of the medicine.

A copy of the questionnaire used in the course of the PIL test of **Promazine Syrup** is found attached as **Appendix 2**.

Promazine Hydrochloride 25 mg/5 ml and 50 mg/5 ml Oral Syrup
Promazine hydrochloride

Key Safety Points

- What **Promazine Syrup** is and what it is used for
- Reasons not to take **Promazine Syrup**
- Warnings and precautions related **Promazine Syrup**
- **Promazine Syrup** and it's ingredient
- Other medicines and **Promazine Syrup**
- Discontinuation of **Promazine Syrup**
- Issues concerning **Promazine Syrup** related to Pregnancy, breastfeeding
- Driving and using machines while taking **Promazine Syrup**
- **Promazine Syrup** with alcohol
- How to take **Promazine Syrup**
- What if taken/given extra dose of **Promazine Syrup**
- What if you forgot dose of **Promazine Syrup**
- Storage of medicine
- Use of **Promazine Syrup in children and adolescents**
- Possible side effects of **Promazine Syrup**

Number of subjects:

A total number of 24 participants will be tested. Four participants will be tested in the preliminary stage, and then 10 participants will be tested in the 1st round and 10 participants in the 2nd round. If the testing does not achieve a satisfactory result during the 2nd round of testing, a 3rd round of testing will be necessary.

Target population:

Target demographics of the subjects are healthy volunteers of the English population that could be potential users of who are generally men or women considering the recommendation based on product information. Subjects will be included upon demographic, gender, and educational basis with the aim of creating a relatively heterogeneous population that is more likely to suffer from the condition that calls for treatment with Promazine Syrup. Subjects who work in the following industries: pharmaceutical, medical, market research, will be excluded from the test. Similarly, subjects refusing prescription medication in general will be excluded, too. The medicine given to adults only. Considering this, the target groups, who were considered to be potential users of Promazine Syrup are from age of 18 years and above. Accordingly, adults person (male or female) from age of 18 to 60 years were selected considering the fact that they are the more frequent users of this medicine.

Participants will be recruited by placing an advertisement on a noticeboard in a local library or community center. The participants will be informed about their participation in an important test on patient information.

Number of questions:

A questionnaire will consist of 18 content and 3 structure related questions. Regarding the structure of questions see Appendix 2.

Duration of Interview:

One interview will take up to 35-45 minutes and the time may get extended if needed.

Location:

Rented, quiet and undisturbed location in United Kingdom, London.

Compensation:

Subjects will be appropriately compensated for participation in the tests, which includes transportation expenses.

Responsibilities:

Sponsor:

- Provide finalized word version of the PIL

Contractor:

- Design of a suitable study protocol/questionnaire and mockup based on data from the PIL with a pilot testing on 4 participants.
- Advertising, screening and selection of subjects; interview scheduling
- Individual interviewing of participants in 2 (two) rounds of 10 subjects; interviews will be documented and recorded appropriately.
- Analyses and reporting from tests, with recommendations on modification to PIL as dictated by responses from each round.
- Delivery of the final report: a full report of testing ready for submission to regulatory authority in Europe, which shall include the results of the assessment carried out and PIL drafts annotated to show proposed amendments if required.

Confidentiality:

This protocol and the information linked to the process of user testing are considered as confidential information. Use and disclosure are permitted in special cases defined in the laws or as recorded by the parts, which are participants of the process.

All participants will sign Non-Disclosure agreement and data release agreement based on their agreement and proper understanding.

Result evaluation:

The test results will be summarized and presented to the sponsor for their review.
A satisfactory test outcome is when, for each question, 90% of all participants can find the information requested within the PIL and 90% can also show that they understand and can act upon it.

Appendix 5.1 Interviewee Non-Disclosure Agreement and Data Release Agreement

INTERVIEWEE NON-DISCLOSURE AGREEMENT AND DATA RELEASE AGREEMENT

The undersigned participant hereby agrees and acknowledges that during the interview process, participants may be exposed to strictly confidential information that must be kept confidential. To ensure the protection of such information, and to preserve any confidentiality necessary under patent and/or trade secret laws, it is agreed that;

1. The Confidential Information to be disclosed can be described as and includes: Technical and business information; and details related to the product's manufacture, name, and time of testing.
2. The personal data recorded below can be used only for the purposes of the interview.
3. It's agreed between the interviewer ([redacted] and participants that the interview process can be voice recorded upon participant's agreement in order to verify the results in the future. This can be also recorded with the answer underlined in the document provided to participant with documentation records.

Please fill in the below information (not obligatory):

Last Name:
First Name:
Male/Female:
Date of Birth:
Nationality:
Profession:
Address:
Telephone:
Email:

Do you ever have difficulty reading the package leaflet that comes with medication?

Do you use written documentation at your job?

Have you ever taken prescription medications?

Do you work in the medical profession?

Is English your first language?

Do you experience any symptoms related to Covid?

Signed this____day of_____, 20_____.

Name/Signature:

Appendix 5.2 Answer Sheet

Question #1 Imagine you are pregnant; meanwhile, you are also taking **Promazine Syrup**. What does the leaflet advise in this condition?

The correct information is located in **Section 2. What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **Pregnancy and breast-feeding**

If you are pregnant or breastfeeding, 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 breastfeeding unless your doctor feels it is absolutely necessary.
The following symptoms may occur in newborn babies, of mothers who have used promazine in the last trimester (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.

Question #2 What information does the leaflet provide regarding the intended use of this medication?

The correct information is located in **Section 1. What Promazine Syrup is and what it is used for**

The name of your medicine is Promazine hydrochloride 25 mg/5 ml or 50 mg/5 ml Oral Syrup (referred to as Promazine Syrup in this leaflet). It contains promazine hydrochloride. This belongs to a group of medicines called phenothiazines.
Promazine can be used to calm your emotions, particularly if you feel restless and agitated.

Question #3 Does this leaflet provide any advice in case if you stop taking **Promazine Syrup** without talking with your doctor?

The correct information is located in **Section 3. How to take Promazine Syrup**
The relevant information regarding this question is: **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 about the use of this medicine, ask your doctor, pharmacist or nurse.

Question #4 Suppose you have phaeochromocytoma and your doctor prescribed you **Promazine Syrup**. In such case, what does the leaflet advise?

The correct information is located in **Section 2. What you need to know before you take Promazine Syrup**

The relevant information regarding this question is: **Do not take Promazine Syrup and tell your doctor if**

- you have a tumour of your adrenal gland that causes high blood pressure (phaeochromocytoma)

Question #5 You are having yellowing of skin and whites of your eyes after starting treatment with **Promazine Syrup**. Does this leaflet give any information about these side effects?

The correct information is located in **Section 4. Possible side effect**
Like all medicines, Promazine can cause side effects, although not everybody gets them.

Stop taking Promazine Syrup straight away and see your doctor if:
[…….]

- **you have any of the following symptoms:**
  - yellowing of the skin and whites of your eyes (jaundice) with fever and possible liver damage.

[OR]

The correct information is located in **Section 4. Possible side effect**

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

[…….]

Reporting side effects

If you get any side effects, talk to your doctor or 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.

[OR]

The correct information is located at the **top of the leaflet**

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

[…….]

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Question #6 Imagine you are taking cimetidine to treat stomach problems. Your new doctor prescribes **Promazine Syrup**. What does the leaflet advise?

The correct information is located in **Section 2. What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **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:
[…….]

- medicines used to treat stomach problems such as cimetidine and cisapride.

Question #7 Does the leaflet provide any guidance on what to do if you take more than the suggested dose of medication?

The correct information is located in **Section 3**. **How to take Promazine Syrup**
The relevant information regarding this question is: **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.

Question #8 Your brother is alcohol addictive, doctor prescribed him this medication. What does the leaflet say about this?

The correct information is located in **Section 2**. **What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **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.

Question #9 You are unable to sleep with constipation and dry mouth after you started treatment with **Promazine Syrup**. Does the leaflet say something about this side effect?

The correct information is located in **Section 4. Possible side effect**
Like all medicines, Promazine can cause side effects, although not everybody gets them.

Stop taking Promazine Syrup straight away and see your doctor if:
[…….]

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

[OR]

The correct information is located in **Section 4. Possible side effect**

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

[……..]

Reporting side effects

If you get any side effects, talk to your doctor or 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.

[OR]

The correct information is located at the **top of the leaflet**

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

[…….]

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Question #10 Suppose your father is suffering from AIDS and taking ritonavir alongside **Promazine Syrup**. In this case, what does the leaflet advise?

The correct information is located in **Section 2. What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **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:
- ritonavir, used to treat HIV and AIDS

Question #11 What does the leaflet say about the storage, expiry, and disposal of **Promazine Syrup**?

The correct information is located in **Section 5. How to store Promazine Syrup**

Keep this medicine out of the sight and reach of children.

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

Store below 25ºC. Store in the original bottle in order to protect from light.

After the first opening of the bottle, the syrup can be stored for 15 days.

Do not use this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Question #12 You forgot to take afternoon dose of **Promazine Syrup**. Does the leaflet give any information on it?

The correct information is located in **Section 3**. **How to take Promazine Syrup**
The relevant information regarding this question is: **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.

Question #13 Does this medication guide provide any details about use of this medication in children and adolescents?

The correct information is located in **Section 3. How to take Promazine Syrup**
Adults
- The recommended dose for adults is 100mg to 200mg four times a day
- In elderly patients the recommended dose is 25mg to 50mg up to 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
- The lowest effective dose for the shortest period possible should be used.

[OR]

Children
This product should not be given to children.

Question #14 What does the leaflet advice regarding driving and using machines while taking **Promazine Syrup**?

The correct information is located in **Section 2. What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **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.

Question #15 Imagine your wife has Parkinson's Disease and her doctor prescribed **Promazine Syrup.** What does the leaflet advise or warn?

The correct information is located in **Section 2: What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **Warnings and precautions**

Talk to your doctor or pharmacist before taking Promazine Syrup, if:
- you have Parkinson's Disease

Question #16 Suppose your father has kidney problems and his doctor prescribed **Promazine Syrup**. What does the leaflet advise or warn?

The correct information is located in **Section 2: What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **Warnings and precautions**

Talk to your doctor or pharmacist before taking Promazine Syrup, if:
- you have kidney problems

Question #17 Does this leaflet give any guidance on how to take **Promazine Syrup**?

The correct information is located in **Section 3: How to take Promazine Syrup**
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Taking this medicine
- This medicine contains either 25mg or 50mg of promazine hydrochloride in each 5 ml.
- Take this medicine by mouth
- Use the dosing cup supplied in the pack
- 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.

[OR]

The relevant information regarding this question is: **Instructions for use: measuring cup**

1. Shake the bottle well before use.
2. Fill the measuring cup to the millilitre (ml) dose marker prescribed by your doctor.
3. Swallow the dose of syrup.

Question #18 Is there any information in this leaflet about the ingredients?

The correct information is located in **Section 2. What you need to know before you take Promazine Syrup**
The relevant information regarding this question is: **Promazine Syrup contains:**

- Methyl hydroxybenzoate (E218), Ethyl hydroxybenzoate (E214) and Propyl hydroxybenzoate (E216). May cause allergic reactions (possibly delayed).
- Propylene glycol (E1520). This medicine contains 100mg propylene glycol in each 5ml.
- Liquid glucose. This medicine contains 250mg 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 medicinal product. May be harmful to the teeth.

- Sucrose. This medicine contains 2.38g 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. May be harmful to the teeth.

Question #19 What are the good points of this leaflet?

Question #20 What are the bad points of this leaflet?

Question #21 On a scale of 1 to 5 how you would rate this leaflet if 1 is very easy and 5 is very difficult?

Appendix 6 Demographics by Individual Participant

	Gender	Age	Education Level
Round 1			
Round 1, Participant 1	M	28	College
Round 1, Participant 2	F	44	School
Round 1, Participant 3	F	25	School
Round 1, Participant 4	M	29	School
Round 1, Participant 5	M	26	College
Round 1, Participant 6	F	39	College
Round 1, Participant 7	F	60	School
Round 1, Participant 8	M	46	College
Round 1, Participant 9	F	53	School
Round 1, Participant 10	M	43	College
Round 2			
Round 2, Participant 1	M	56	College
Round 2, Participant 2	F	26	College
Round 2, Participant 3	M	46	School
Round 2, Participant 4	F	31	College
Round 2, Participant 5	M	54	School
Round 2, Participant 6	F	52	College
Round 2, Participant 7	F	44	School
Round 2, Participant 8	M	22	College
Round 2, Participant 9	F	39	School
Round 2, Participant 10	M	25	College

Appendix 7 Free Oral Opinion

The following are participant responses to the final three questions which solicit overall feedback regarding the package leaflet.

Round 1

Participant 1
Positive: It is pretty well structured.
Negative: None
Rating: 1

Participant 2
Positive: Good document and information.
Negative: There is a lot of information
Rating: 2

Participant 3
Positive: Very specific and scientific
Negative: None
Rating: 1

Participant 4
Positive: Great**.** Very clear and I enjoyed participation
Negative: None
Rating: 2

Participant 5
Positive: Very informative
Negative: None
Rating: 2

Participant 6
Positive: The headings make it quite clear to read
Negative: None
Rating: 2

Participant 7
Positive: It is clear and understandable
Negative: None
Rating:1

Participant 8
Positive: Good
Negative: None
Rating: 1

Participant 9
Positive: It is easy to read and find information
Negative: None
Rating: 1

Participant 10
Positive: It is very easy to read
Negative: None
Rating: 1

Round 2

Participant 1
Positive: Good to understandable
Negative: None
Rating: 1

Participant 2
Positive: Nice. I link it. That it good informative leaflet
Negative: None
Rating: 1

Participant 3
Positive: Clear to me
Negative: None
Rating: 2

Participant 4
Positive: It is well laid out and easy to find information
Negative: None
Rating: 2

Participant 5
Positive: It is easy and will be useful to patients
Negative: None
Rating: 1

Participant 6
Positive: Very precise
Negative: None
Rating: 1

Participant 7
Positive: quick to get information from leaflet
Negative: None
Rating: 1

Participant 8
Positive: Good document
. Its need some time to review but its good
Negative: None
Rating: 1

Participant 9
Positive: Easy to read follow by me
Negative: None
Rating: 2

Participant 10
Positive: Easy to follow. Lots of information
Negative: None
Rating: 1

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Space for Pharma code

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 or pharmacist.
- 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 or pharmacist. 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

The name of your medicine is Promazine hydrochloride 25 mg/5 ml or 50 mg/5 ml Oral Syrup (referred to as Promazine Syrup in this leaflet). It contains promazine hydrochloride. This belongs to a group of medicines called phenothiazines.

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

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

Do not take Promazine Syrup and tell your doctor if:
- you are allergic (hypersensitive) 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
- you are pregnant or breastfeeding
- 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
- you have a tumour of your adrenal gland that causes high blood pressure (phaeochromocytoma)
- you have dulled senses such as feeling sleepy or uncoordinated, having blurred vision, slurred speech or being less aware of your surroundings (CNS depression).
- if you have moderate or severe liver problems
- if you have heart problems such as an unusually fast heartbeat or unstable blood pressure, causing dizziness, light-headedness or fainting.

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 or pharmacist 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 the formation of blood clots
- you have heart problems including unusual heartbeats, 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
- if 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 heartbeats) 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 maprolitine, pimozide, 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 hay fever (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 from 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 breastfeeding, 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 breastfeeding unless your doctor feels it is absolutely necessary.

The following symptoms may occur in newborn babies, of mothers who have used promazine in the last trimester (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:

Promazine Syrup contains:
- Methyl hydroxybenzoate (E218), Ethyl hydroxybenzoate (E214) and Propyl hydroxybenzoate (E216). May cause allergic reactions (possibly delayed).
- Propylene glycol (E1520). This medicine contains 100mg propylene glycol in each 5ml.
- Liquid glucose. This medicine contains 250mg 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 medicinal product. May be harmful to the teeth.
- Sucrose. This medicine contains 2.38g 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. May be harmful to the teeth.

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3. How to take Promazine Syrup:
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine
- This medicine contains either 25mg or 50mg of promazine hydrochloride in each 5 ml.
- Take this medicine by mouth
- Use the dosing cup supplied in the pack
- 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
- In elderly patients the recommended dose is 25mg to 50mg up to 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
- The lowest effective dose for the shortest period possible should be used.

Children
This product should not be given to children.

Instructions for use: measuring cup
1. Shake the bottle well before use.
2. Fill the measuring cup to the millilitre (ml) dose marker prescribed by your doctor.
3. Swallow the dose of syrup.

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 about 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 Promazine Syrup 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 heartbeat, 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, unusual tiredness, yellowing of the skin, weakness or breathlessness
- heart changes including fast heartbeats, unusual heartbeats, and 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 walking 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 n 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 or 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.
Do not use this medicine after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Store below 25ºC. Store in the original bottle in order to protect from light.
After the first opening of the bottle, the syrup can be stored for 15 days.
Do not use this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
What Promazine Syrup contains
The active substance is promazine hydrochloride. Each 5ml of the syrup contains 25 mg or 50 mg of promazine hydrochloride.
The other ingredients are propylene glycol (E1520), methyl para hydroxybenzoate (E218), ethyl para hydroxybenzoate (E214), propyl para hydroxybenzoate (E216), sucrose, liquid glucose, ascorbic acid (E300), tutti frutti flavour and purified water.

What Promazine Syrup looks like and contents of the pack
Promazine hydrochloride 25 mg/5 ml and 50 mg/5 ml oral syrup is a colourless to orange-brown colour syrup.
Each carton contains 1 amber glass bottle with a child-resistant cap and a 30 ml measuring cup (graduated at every 2.5 ml equivalent to either 12.5 mg or 25 mg promazine hydrochloride).

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