UK Risk Management Plan for Docusate Sodium 100mg Capsules

RMP version to be assessed as part of this application:

RMP Version number: 1.0

Data lock point for this RMP: 27-August-2024

Date of final sign off: 29-August-2024

QPPV name: [redacted]

QPPV signature: [redacted]

Part I: Product(s) Overview

Table Part I.1 – Product Overview

Active substance(s) **(INN or common name)**	Docusate Sodium 100mg Capsules
Pharmacotherapeutic group(s) (ATC Code)	ATC code: A06AA02 softeners, emollients
Marketing Authorisation Applicant	IILCO (UK) LIMITED
Medicinal products to which this RMP refers	1
Invented name(s) in the European Economic Area (EEA)	Docusate Sodium 100mg Capsules
Marketing authorisation procedure	National
Hyperlink to the Product Information	SPC and PIL are attached
Indication(s) in the UK	a) To prevent and treat chronic constipation. (i) to soften hard, dry stools in order to ease defaecation and reduce straining at stool; and (ii) in the presence of haemorrhoids and anal fissure, to prevent hard, dry stools and reduce straining. b) As an adjunct in abdominal radiological procedures.
Dosage in the EEA	**Docusate Sodium 100mg Capsules** Adults: Up to 500 mg should be taken daily in divided doses. Treatment should be commenced with large doses, which should be decreased as the condition of the patient improves. For use with barium meals: 400 mg to be taken with the meal. Elderly: As for adults. Paediatric population: The safety and efficacy of Dioctyl in children aged 0 to 11 years have not yet been established. No data are available.

	Method of administration For oral use.
Pharmaceutical form(s) and strengths	Capsule, soft. A two colour (opaque white and opaque yellow) soft, oval, gelatin capsule with a clear, colourless liquid fill.
Is/will the product be subject to additional monitoring in the UK?	No

Part II: Safety specification

The Marketing Authorization (MA) application Docusate Sodium 100mg Capsules is being submitted under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

Part II: Module SI - Epidemiology of the indication(s) and target population(s)

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

Part II: Module SII - Non-clinical part of the safety specification

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

Part II: Module SIII - Clinical trial exposure

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

Part II: Module SIV - Populations not studied in clinical trials

None

SIV.1 Exclusion criteria in pivotal clinical studies within the development programme

None

SIV.2 Limitations to detect adverse reactions in clinical trial development programmes

The applicant's product is a generic version of the Docusate Sodium 100mg Capsules, [redacted] and hence there is no data to present for this section.

SIV.3 Limitations in respect to populations typically under-represented in clinical trial development programmes

The applicant's product is a generic version of the Docusate Sodium 100mg Capsules, [redacted] and hence there is no data to present for this section.

Part II: Module SV - Post-authorisation experience

SV.1 Post-authorisation exposure

Not applicable. The product is not authorised for marketing, yet. This is the first version of the RMP.

Part II: Module SVI - Additional EU requirements for the safety specification

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.1 Potential for harm from overdose

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.2 Potential for transmission of infectious agents

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.3 Potential for misuse for illegal purposes

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.4.1 Potential for medication errors

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.4.2 Preventive measures for the final product(s) being marketed

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.5 Potential for off-label use

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

VI.6 Specific Paediatric issues

Not applicable – no paediatric investigation plan is in place for applicant's docusate sodium.

VI.7 Conclusions

None

Part II: Module SVII - Identified and potential risks

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

SVII.1 Identification of safety concerns in the initial RMP submission

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

SVII.2 New safety concerns and reclassification with a submission of an updated RMP

This section is not applicable for initial marketing authorisation application as this application is being submitted as generic, under article 10(1) of Directive 2001/83/EC and Directive 2010/84/EU.

Part II: Module SVIII - Summary of the safety concerns

Table SVIII.1: Summary of safety concerns

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

Part III: Pharmacovigilance Plan (including post-authorisation safety studies)

III.1 Routine pharmacovigilance activities

The objective of pharmacovigilance strategy is to systematically collect ADRs from multiple sources and to conduct real time and periodic medical assessments of single and aggregate cases to identify potential safety signals. Early detection of safety signals enables MA holder to develop and implement appropriate risk management strategy. The objective of the routine surveillance program conducted by the MA holder is to systematically review safety data from multiple sources. The purpose of surveillance is to detect and evaluate changes in reporting frequency of AEs and changes in overall adverse event pattern suggestive of potentially new safety concerns.

The routine pharmacovigilance practices comply with the pharmacovigilance practices covered in regulations 2010/84; 1235/2010 and the associated "Guidelines on good pharmacovigilance practices (GVP)".

III.2 Additional pharmacovigilance activities

Not applicable

III.3 Summary Table of additional Pharmacovigilance activities

Not applicable

Part IV: Plans for post-authorisation efficacy studies

Not applicable. No post-authorisation efficacy studies are planned by the MAH. No studies have been imposed by the CHMP or national competent authority or are Specific Obligations.

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

The safety information in the proposed product information is aligned to the reference medicinal product.

V.1. Routine Risk Minimisation Measures

Table Part V.1: Description of routine risk minimisation measures by safety concern Important identified risks	
Safety concern	**Risk minimisation measures**
None	None

Important potential risks	
Safety concern	**Risk minimisation measures**
None	None

Missing information	
Safety concern	**Risk minimisation measures**
None	None

V.2. Additional Risk Minimisation Measures

None

V.3 Summary of risk minimisation measures

Table Part V.3: Summary table of pharmacovigilance activities and risk minimisation activities by safety concern.

Part V.1: Description of routine risk minimisation measures by safety concern

Important identified risks	
Safety concern	**Risk minimisation measures**
None	None

Important potential risks	
Safety concern	**Risk minimisation measures**
None	None

Missing information	
Safety concern	**Risk minimisation measures**
None	None

Part VI: Summary of the risk management plan

Summary of risk management plan for Docusate Sodium 100mg Capsules

This is a summary of the risk management plan (RMP) for Docusate Sodium 100mg Capsules. The RMP details important risks of Docusate Sodium 100mg Capsules, routine risk minimisation activities recommending specific clinical measures to address the risk. Routine Pharmacovigilance will be used to ensure that all suspected adverse reactions to docusate sodium are collected, collated and reported to the agency in accordance with the regulatory requirements; either as expedited reports or PSURs as appropriate.

Continuous monitoring of safety profile including signal detection and analysis will be carried out to determine if any updating of labelling is required and/or liaison with the agency for risks and uncertainties (missing information).

Docusate Sodium 100mg Capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Docusate Sodium 100mg Capsules should be used.

I. The medicine and what it is used for

It contains 100mg docusate sodium as the active substance, and it is given by oral route as Docusate Sodium 100mg Capsules.

In adults the initial dose is up to 500 mg and should be taken daily in divided doses. Treatment should be commenced with large doses, which should be decreased as the condition of the patient improves. For use with barium meals: 400 mg to be taken with the meal.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

[redacted]

[redacted]

II.A List of important risks and missing information

Outlined in section II.B

II.B Summary of important risks

The safety information in the proposed product Information is aligned to the reference medicinal product.

Important identified risks	
Safety concern	**Risk minimisation measures**
None	None

Important potential risks	
Safety concern	**Risk minimisation measures**
None	None

Missing information	
Safety concern	**Risk minimisation measures**
None	

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable

II.C.2 Other studies in post-authorisation development plan

Not applicable

Part VII: Annexes

Table of contents

Annex 1 – EudraVigilance Interface

Not applicable

Annex 2 – Tabulated summary of planned, ongoing, and completed pharmacovigilance study programme

Not applicable

Annex 3 - Protocols for proposed, on-going and completed studies in the pharmacovigilance plan

Not applicable

Annex 4 - Specific adverse drug reaction follow-up forms

Not applicable

Annex 5 - Protocols for proposed and on-going studies in RMP part IV

Not applicable

Annex 6 - Details of proposed additional risk minimisation activities (if applicable)

Not applicable

Annex 7 - Other supporting data (including referenced material)

1. Guideline on good pharmacovigilance practices (GVP) Module V – Risk management systems (Rev 2); 28 March 2017; EMA/838713/2011 Rev 2*
2. Good practice guide on risk minimisation and prevention of medication errors; 18 November 2015; EMA/606103/2014; Pharmacovigilance Risk Assessment Committee (PRAC)

Annex 8 – Summary of changes to the risk management plan over time

Not applicable