

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Macrogol powder for oral solution:

Macrogols are high molecular weight (4000), long linear polymers to which water molecules bind by means of hydrogen bonds. The contents of each sachet are dissolved in water just before use and administered orally. After oral administration, the volume of intestinal fluids increases and the volume of unabsorbed intestinal fluid accounts for the laxative properties of the macrogol solution.

This is a summary of the risk management plan (RMP) for Macrogol 4000, 4 g and 10 g powder for oral solution. There are no safety concerns identified for this product. Macrogol 4000, 4 g/10 g powder for oral solution's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how macrogol 4000 should be used.

This summary of the RMP for Macrogol 4000 powder for oral solution should be read in the context of all this information including

I. The medicine and what it is used for:

Macrogol 4000, powder for oral solution is indicated for the treatment of constipation. Macrogol 4000, 4 g powder is used as a symptomatic treatment for constipation in children aged between 6 months and 8 years and 10 g powder is used as a symptomatic treatment of constipation in adults and children aged 8 years and above.

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

There are no important identified risks, important potential risks and missing information identified for macrogol 4000, powder for oral solution.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (SmPC) addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without Prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A. List of important risks and missing information

Important risks of macrogol 4000 are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is enough proof of a link with the use of macrogol 4000. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table 2: Summary of safety concerns

There are no important identified risks, important potential risks and missing information identified for macrogol 4000, powder for oral solution.

Important Identified Risks	<ul style="list-style-type: none"> • None
Important Potential Risks	<ul style="list-style-type: none"> • None
Missing Information	<ul style="list-style-type: none"> • None

II.B. Summary of important risks

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

II.C. Post authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of macrogol 4000, powder for oral solution.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for macrogol 4000, powder for oral solution.