

7 Part VI: Summary of the risk management plan (RMP) - Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate, 13.125 g + 351 mg + 47 mg + 179 mg, Powder for oral solution

This is a summary of the RMP for Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate, 13.125 g + 351 mg + 47 mg + 179 mg, powder for oral solution. The RMP details important risks of Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution, how these risks can be minimized, and how more information will be obtained about Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate's risks and uncertainties (missing information).

Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution's summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution should be used.

Important new concerns or changes to the current ones will be included in updates of the Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution's RMP.

7.1 Part VI: I. The medicine and what it is used for

Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution is a laxative that makes your feces softer and easier to pass, giving you relief from constipation (a condition of the digestive system characterized by hard feces that are difficult to pass). The electrolytes (salts) help to maintain your body's normal levels of sodium, potassium and water while you are being treated for constipation.

Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution is indicated for adults, adolescents and elderly. It is not recommended for children below 12 years of age.

It contains Macrogol 3350, Sodium Chloride, Potassium Chloride and Sodium Hydrogen Carbonate as active substances and is given orally as powder for oral solution (13.125 g + 351 mg + 47 mg + 179 mg).

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

Important risks of Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution, together with measures to minimize such risks are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;

- Important advice on the medicine’s packaging;
- The authorized pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Reports (PSURs) assessment (if applicable) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution is not yet available, it is listed under ‘missing information’ below.

7.2.1 Part VI – II.A: List of important risks and missing information

Important risks of Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Macrogol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution. 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 7-1 List of important risks and missing information

Important identified risks	Hypersensitivity reactions including anaphylaxis
	Fluid/electrolyte shifts, including hyperkalemia and hypokalemia
Important potential risks	Drug interactions
	Dehydration
Missing information	Use in pregnancy and lactation

7.2.2 Part VI – II.B: Summary of important risks

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

7.2.3 Part VI – II.C: Post-authorization development plan**7.2.3.1 II.C.1 Studies which are conditions of the marketing authorization**

There are no studies which are conditions of the marketing authorization or specific obligation of Macroglol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution.

7.2.3.2 II.C.2. Other studies in post-authorization development plan

There are no studies required for Macroglol 3350 + Sodium Chloride + Potassium Chloride + Sodium Hydrogen Carbonate powder for oral solution.