

Part VI: Summary of the risk management plan

Summary of risk management plan for MOVICOL[®] product range (macrogol 3350)

This is a summary of the risk management plan (RMP) for MOVICOL[®] product ranges (MOVICOL[®], MOVICOL[®] Chocolate, MOVICOL[®] Plain, MOVICOL[®] Paediatric, MOVICOL[®] Paediatric Chocolate, MOVICOL[®] Paediatric Plain, MOVICOL[®] Half, MOVICOL[®] 6.9 g, MOVICOL[®] Liquid, MOVICOL[®] Ready to Take. In Germany, MOVICOL[®] is branded as ISOPEG and MACROLYTE. The RMP details important risks of MOVICOL[®] product ranges and how these risks can be minimised, and how more information will be obtained about MOVICOL[®] product range risks and uncertainties (missing information).

MOVICOL[®]'s summary of product characteristics (SmPC) and its package leaflet gives essential information to healthcare professionals and patients on how MOVICOL[®] product ranges should be used.

I. The medicine and what it is used for

MOVICOL[®] is a laxative for the treatment of constipation in adults, children, adolescents and elderly. MOVICOL[®] helps you to have a comfortable bowel movement even if you have been constipated for a long time. MOVICOL[®] also works in very bad constipation called faecal impaction. MOVICOL[®] contains macrogol 3350 as the active substance and it is taken orally and can be taken at any time with or without food.

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

Important risks of MOVICOL[®] product ranges, together with measures to minimise such risks and the proposed studies for learning more about MOVICOL[®] product range risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 MOVICOL[®] product range is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of MOVICOL[®] product ranges are risks that need special risk management activities to further investigate or minimise 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 MOVICOL[®] product range. 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).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

There are no important identified risks or important potential risks currently for the MOVICOL[®] product range.

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 the MOVICOL[®] product range.

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

There are no studies required for the MOVICOL[®] product range.