Summary of risk management plan for Omnicol (macrogol 3350)

This is a summary of the risk management plan (RMP) for Omnicol. The RMP details important risks of Omnicol, how these risks can be minimised, and how more information will be obtained about Omnicol's risks and uncertainties (missing information).

Omnicol's summaries of product characteristics (SmPC) and their package leaflets give essential information to healthcare professionals and patients on how Omnicol should be used.

I. The medicine and what it is used for

Omnicol 13.8 g is authorised for chronic constipation, and Omnicol 6.9 g is authorised for chronic constipation in children from 1 to 11 years old (see SmPC for the full indication). It contains macrogol 3350, sodium chloride, sodium hydrogen carbonate, and potassium chloride as active substances and it is given as a powder for oral solution provided in sachets.

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

Important risks of Omnicol, together with measures to minimise such risks and the proposed studies for learning more about Omnicol's 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.

If important information that may affect the safe use of Omnicol is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Omnicol 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 Omnicol. 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

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 Omnicol.

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

There are no studies required for Omnicol.