Summary of risk management plan for Pegorion 6 g and 12 g powder for oral solution, sachet (macrogol 4000) Orion Corporation

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

Pegorion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pegorion should be used.

Important new concerns or changes to the current ones will be included in updates of Pegorion's RMP.

I. The medicine and what it is used for

Pegorion is authorised for:

- Treatment of chronic constipation.
- Disintegration and softening of the dried, hard faeces (treatment of coprostasis/faecal impaction).

It contains macrogol 4000 as the active substance and it is given by mouth.

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

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

II.A List of important risks and missing information

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

Safety concerns are adequately addressed in the product information.

II.B Summary of important risks

Safety concerns are adequately addressed in the product information.

II.C Post-authorisation development plan

There are no studies required for Pegorion.