Part VI: Summary of the risk management plan

Summary of risk management plan for Levolac 670 mg/ml oral solution (lactulose)

This is a summary of the risk management plan (RMP) for Levolac 670 mg/ml oral solution. The RMP details important risks of Levolac, how these risks can be minimized, and how more information will be obtained about Levolac's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Levolac is indicated for symptomatic treatment of constipation, and treatment of hepatic encephalopathy.

It is indicated in adults, and in children and adolescents aged 1 month to 17 years only for the treatment of constipation.

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

See SmPC for the full information.

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

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

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*.

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 Levolac.