Part VI: Summary of the risk management plan

Summary of risk management plan for Folsyre Sandoz (folic acid)

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

Folsyre Sandoz's summary of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals and patients on how Folsyre Sandoz tablets should be used.

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

I. The medicine and what it is used for

Folsyre Sandoz is authorised for:

For the primary prevention of neural tube defects in the foetus for women planning a pregnancy.

Prophylactic treatment before and during pregnancy when there is an increased risk for neural tube defects in the foetus.

Treatment of folate deficiency states (e.g., folate deficient megaloblastic anaemia) confirmed by blood test including B_{12} status in adults, adolescents and children from 6 years old.

Prophylaxis of drug-induced folate deficiency in adults, adolescents and children from 6 years old. (see SmPC for the full indication).

It contains folic acid as the active substance, and it is taken orally as tablets (1 mg, 5 mg).

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

Important risks of Folsyre Sandoz, together with measures to minimise such risks and the proposed studies for learning more about Folsyre Sandoz'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 analyzed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities**.**

II.A List of important risks and missing information

Important risks of Folsyre Sandoz 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 Folsyre Sandoz. 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

Not applicable.

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 Folsyre Sandoz.

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

There are no studies required for Folsyre Sandoz.