Part VI: Summary of the risk management plan

Summary of risk management plan Lamotrigine 5/25/100 mg chewable/dispersible tablets (Lamotrigine)

This is a summary of the risk management plan (RMP) for Lamotrigine 5/25/100 mg chewable/dispersible tablets. The RMP details important risks of Lamotrigine 5/25/100 mg chewable/dispersible tablets, how these risks can be minimised, and how more information will be obtained about Lamotrigine 5/25/100 mg chewable/dispersible tablets and uncertainties (missing information).

Lamotrigine 5/25/100 mg chewable/dispersible tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Lamotrigine 5/25/100 mg chewable/dispersible tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Lamotrigine 5/25/100 mg chewable/dispersible tablet's RMP.

I. The medicine and what it is used for

Lamotrigine 5/25/100 mg chewable/dispersible tablets are indicated for following indications:

Epilepsy

Adults and adolescents aged 13 years and above

- Adjunctive or monotherapy treatment of partial seizures and generalised seizures, including tonic‑clonic seizures.
- Seizures associated with Lennox‑Gastaut syndrome. Lamotrigine chewable/dispersible tablets are given as adjunctive therapy but may be the initial antiepileptic drug (AED) to start with in Lennox‑Gastaut syndrome.

Children and adolescents aged 2 to 12 years

- Adjunctive treatment of partial seizures and generalised seizures, including tonic‑clonic seizures and the seizures associated with Lennox‑Gastaut syndrome.
- Monotherapy of typical absence seizures.

Bipolar disorder

Adults aged 18 years and above

- Prevention of depressive episodes in patients with bipolar I disorder who experience predominantly depressive episodes.

Lamotrigine chewable/dispersible tablets are not indicated for the acute treatment of manic or depressive episodes.

It contains lamotrigine as the active substance and it is given orally.

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

Important risks of Lamotrigine 5/25/100 mg chewable/dispersible tablets, together with measures to minimise such risks and the proposed studies for learning more about Lamotrigine 5/25/100 mg chewable/dispersible tablet'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 signal management activity, 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 Lamotrigine 5/25/100 mg chewable/dispersible tablets 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 Lamotrigine 5/25/100 mg chewable/dispersible tablets. 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).

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 authorization or specific obligation of Lamotrigine 5/25/100 mg chewable/dispersible tablets.

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

There are no studies required for Lamotrigine 5/25/100 mg chewable/dispersible tablets as post-authorisation development plan.