Part VI: Summary of the risk management plan

Summary of risk management plan for Lamotrigin PTR Pharma 5/100 mg tablets

This is a summary of the risk management plan (RMP) for Lamotrigin PTR Pharma 5/100 mg tablets.

The RMP details important risks of Lamotrigin PTR Pharma 5/100 mg tablets, how these risks can be minimised, and how more information will be obtained about Lamotrigin PTR Pharma 5/100 mg tablets' risks and uncertainties (missing information).

Lamotrigin PTR Pharma 5/100 mg tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Lamotrigin PTR Pharma 5/100 mg tablets should be used.

I. The medicine and what it is used for

Lamotrigin PTR Pharma 5/100 mg tablets are authorized for epilepsy in adults, adolescents and children aged 2 years and above for the treatment of partial seizures and generalized seizures, including tonic-clonic seizures as well as for the treatment of seizures associated with Lennox-Gastaut syndrome. Further, Lamotrigin PTR Pharma 5/100 mg tablets are authorized for the treatment of bipolar disorder in adults aged 18 and above for prevention of depressive episodes. (see SmPC for full indication)

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 Lamotrigin PTR Pharma 5/100 mg tablets, together with measures to minimise such 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 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 Lamotrigin PTR Pharma 5/100 mg tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Lamotrigin PTR Pharma 5/100 mg 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).

Summary of safety concerns	
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 obligations of Lamotrigin PTR Pharma 5/100 mg tablets.

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

There are no studies required for Lamotrigin PTR Pharma 5/100 mg tablets.