# Part VI Summary of risk management plan for lamotrigine Oral Suspensions

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

Lamotrigine 5mg/1ml, 10mg/ml and 20mg/ml Oral Suspensions summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Lamotrigine Oral Suspensions should be used.

## I. The medicine and what it is used for

Lamotrigine 5mg/ml, 10mg/ml and 20mg/ml Oral Suspensions are intended for treatments of epilepsy for those 2 years of age or older and bipolar disorder for those 18 years of age or older. (see SmPC for the full indications). It contains Lamotrigine as the active substance and it is given by oral administration.

## II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Lamotrigine 5mg/ml, 10mg/ml and 20mg/ml Oral Suspensions, together with measures to minimize such risks are outlined below:

Measures to minimise the risks identified for Lamotrigine Oral Suspension 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. If important information that may affect the safe use of Lamotrigine Oral Suspensions is not yet available, it is listed under 'missing information' below."

## II.A List of important risks and missing information

Important risks of Lamotrigine 5mg/ml,10mg/ml and 20mg/ml Oral Suspensions 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 Oral Suspension. 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

Syri Pharma Limited has updated the risk management plan to align with RMP version 1.0 for Lamotrigine 5/25/100 mg chewable/dispersible tablets (available from laegemiddelstyrelsen.dk) and RMP version 2.1 for Lamotrigine Products (LAMICTAL and associated names, LAMBIPOL) (available from fimea.fi).

## 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 Lamotrigine 5mg/ml, 10mg/ml and 20mg/ml Oral Suspension.

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

There are no studies required for Lamotrigine 5mg/ml, 10mg/ml and 20mg/ml Oral Suspensions and there is no post authorisation development plan.