Part VI: Summary of the risk management plan

Summary of risk management plan for Pregabalin EQL Pharma

This is a summary of the risk management plan (RMP) for Pregabalin EQL Pharma. The RMP details important risks of Pregabalin EQL Pharma and how more information will be obtained about Pregabalin EQL Pharma's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Pregabalin EQL Pharma is authorised for neuropathic pain, epilepsy and generalized anxiety disorder (see SmPC for the full indication). It contains pregabalin as the active substance and it is given by hard capsules.

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

Important risks of Pregabalin EQL Pharma, together with measures to minimise such risks and the proposed studies for learning more about Pregabalin EQL Pharma'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 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 Pregabalin EQL Pharma are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely orally 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 Pregabalin EQL Pharma. 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	Dizziness, somnolence, loss of consciousness, syncope and potential for accidental injury Discontinuation events Drug interactions (lorazepam, ethanol and CNS depressants) Euphoria Congestive heart failure Vision-related events Abuse, misuse and dependence
Important potential risks	Suicidality Off-label use in children
Missing information	Use during pregnancy and breastfeeding

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

NA

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 Prebagalin EQL Pharma

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

There are no studies required for Prebagalin EQL Pharma