Part VI: Summary of the risk management plan

Summary of risk management plan for Pregabalin

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

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

I. The medicine and what it is used for

Pregabalin is authorised for peripheral and central neuropathic pain, for epilepsy and generalised anxiety disorder in adults (see SmPC for the full indication). It contains pregabalin as the active substance and it is given by mouth. Pregabalin capsules, hard are available in strengths of 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg.

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

Important risks of pregabalin, together with measures to minimise such risks and the proposed studies for learning more about pregabalin'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. A targeted follow-up questionnaire for pregabalin abuse, misuse, dependence and withdrawal symptoms has been set in place. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of pregabalin is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of pregabalin 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 pregabalin. 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	• Weight gain • Peripheral oedema and oedema-related events • Dizziness, somnolence, loss of consciousness, confusion, syncope and potential for accidental injury • Discontinuation events • Drug interactions (lorazepam, ethanol and CNS depressants) • Euphoria • Hypersensitivity and allergic reactions • Congestive heart failure • Vision-related effects • Abuse, misuse and drug dependence
Important potential risks	• Suicidality • Haemangiosarcoma • Off label use in paediatric patients
Missing information	• Pregnancy and lactation

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 obligation of pregabalin.

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

There are no studies required for pregabalin.