Part VI: Summary of the risk management plan

Summary of risk management plan for Prelexa 75 mg, 150 mg hard capsules

This is a summary of the risk management plan (RMP) for Prelexa 75 mg, 150 mg hard capsules. The RMP details important risks of Prelexa 75 mg, 150 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Prelexa 75 mg, 150 mg hard capsules's risks and uncertainties (missing information).
Prelexa 75 mg, 150 mg hard capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prelexa 75 mg, 150 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of [Pregabalin] 25, 50, 75, 100, 150, 200, 225 & 300MG HARD CAPSULES RMP.

I. The medicine and what it is used for

Prelexa 75 mg, 150 mg hard capsules is authorized for neuropathic pain, epilepsy and generalised anxiety disorder. It contains pregabalin 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 [Pregabalin], together with measures to minimise such risks and the proposed studies for learning more about [Pregabalin] 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.

If important information that may affect the safe use of [Pregabalin] is not yet available, it is listed under 'missing information' below.

These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Prelexa 75 mg, 150 mg hard capsules are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Prelexa 75 mg, 150 mg hard capsules. 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 • Vision-related events • Discontinuation events • Congestive heart failure • Euphoria • Drug interactions (lorazepam, ethanol and CNS depressants) • Abuse and drug dependence
Important potential risks	• Suicidality • Off label use in paediatric patients
Missing information	• Pregnancy and lactating women

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 Prelexa 75 mg, 150 mg hard capsules.

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

There are no studies required for Prelexa 75 mg, 150 mg hard capsules.