Part VI: Summary of the risk management plan

Summary of risk management plan for Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules (pregabalin)

This is a summary of the risk management plan (RMP) for Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules. The RMP details important risks of Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules, how these risks can be minimised, and how more information will be obtained about Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsule's risks and uncertainties (missing information).

Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsule's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules should be used.

This summary of the RMP for Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsule's RMP.

I. The medicine and what it is used for

Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules are indicated for the following conditions:

Neuropathic pain

Pregabalin Accord is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy

Pregabalin Accord capsules are is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

Generalised Anxiety Disorder

Pregabalin Accord capsules are indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

It contains pregabalin as the active substance and it is for oral use only.

Further information about the evaluation of Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules benefits can be found in Pregabalin's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage. https://www.ema.europa.eu/en/medicines/human/EPAR/pregabalin-accord

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

Important risks of Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules' 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 including PSUR assessment (if applicable) and signal management activity, 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 Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks Pregabalin Accord 2525mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg 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 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 Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg 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).

Important identified risk (s)	• Dizziness, somnolence, loss of consciousness, syncope and potential for accidental injury • Discontinuation events • Drug interactions (lorazepam, ethanol and CNS depressants) • Congestive heart failure • Euphoria • Vision-related events • Abuse and Drug Dependence
Important potential risk (s)	• 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 authorization or specific obligation of Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules.

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

There are no studies required for Pregabalin Accord 25mg / 50mg / 75mg / 100mg / 150mg / 200mg / 225mg and 300mg hard capsules as post-authorisation development plan.