Summary of Risk Management Plan for Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules

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

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

Important new concerns or changes to the current ones will be included in updates of Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules RMP.

I. The medicine and what it is used for

Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules are indicated for the treatment of following conditions:

Neuropathic pain

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

Epilepsy

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

Generalised anxiety disorder

Pregabalin Jubilant is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules contains Pregabalin as the active substance and it is given by oral route of administration.

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

Important risks of Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules, together with measures to minimise such risks for learning more about Pregabalin Jubilant 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 medicines packaging;
- The authorised pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly.
- The medicines 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.

II.A List of important risks and missing information

Important risks of Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 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 Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules.

Potential risks are concerns for which an association with the use of Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules 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 Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules 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
Important potential risks	• Suicidality • Off-label use in paediatric patients
Missing information	• None

II.B Summary of important risks

The safety information in the current Product Information is aligned to the reference medicinal product (Lyrica hard capsule of Pfizer Limited).

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 Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules.

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

There are no on-going or closed studies for Pregabalin Jubilant 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg hard capsules.