Summary of risk management plan for GABAPENTIN ORION 600 MG AND 800 MG FILM-COATED TABLETS
Gabapentin
Orion Corporation

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

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

Important new concerns or changes to the current ones will be included in updates of Gabapentin Orion's RMP.

I. The medicine and what it is used for

Gabapentin Orion is authorised for the following indications:

Epilepsy

Gabapentin Orion is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults and children aged 6 years and above.

Gabapentin Orion is indicated as monotherapy in the treatment of partial seizures with and without secondary generalization in adults and adolescents aged 12 years and above.

Treatment of peripheral neuropathic pain

Gabapentin Orion is indicated for the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and post-herpetic neuralgia in adults.

It contains gabapentin as the active substance and it is given by oral route.

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

Important risks of Gabapentin Orion, together with measures to minimise such risks and the proposed studies for learning more about Gabapentin Orion'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 Gabapentin Orion 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 Gabapentin Orion. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the 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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Gabapentin Orion.

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

There are no studies required for Gabapentin Orion.