

Part VI: Summary of the risk management plan

Summary of risk management plan for Pregabalin Aristo (pregabalin)

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

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

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

I. The medicine and what it is used for

Pregabalin Aristo is authorised for the treatment of peripheral and central neuropathic pain, as adjunctive therapy in adults with partial seizures with or without secondary generalisation and for treatment of generalised anxiety disorder (see SmPC for the full indication).

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 Aristo, together with measures to minimise such risks and the proposed studies for learning more about Pregabalin Aristo'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*.

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

II.A List of important risks and missing information

Important risks of Pregabalin Aristo 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 Aristo. 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	Abuse and drug dependence Congestive heart failure Discontinuation events Dizziness, somnolence, loss of consciousness, confusion, syncope and potential for accidental injury Drug interactions (lorazepam, ethanol and CNS depressants) Euphoria Vision-related effects
Important potential risks	Off label use in paediatric patients Suicidality
Missing information	Use during 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 Aristo.

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

There are no studies required for Pregabalin Aristo.