Part VI: Summary of the risk management plan

Summary of risk management plan for Nuralgan 500 mg/200 mg film-coated tablets (PARACETAMOL/IBUPROFEN)

This is a summary of the risk management plan (RMP) for Nuralgan 500mg /200 mg film-coated tablets. The RMP details important risks of Nuralgan 500mg /200 mg film-coated tablets, and how more information will be obtained about Nuralgan 500mg /200 mg film-coated tablets's risks and uncertainties (missing information).

Nuralgan 500 mg/200 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nuralgan 500 mg/200 mg film-coated tablets should be used.

I. The medicine and what it is used for

Nuralgan 500 mg/200 mg film-coated tablets are authorized for the short-term symptomatic treatment of mild to moderate pain. This product is especially suitable for pain which requires stronger analgesia than ibuprofen or paracetamol alone. It contains PARACETAMOL and IBUPROFEN as the active substances, and it is given by oral route as film-coated tablets containing 500 mg of paracetamol and 200 mg of ibuprofen.

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

Important risks of Nuralgan 500 mg/200 mg film-coated tablets, together with measures to minimize such risks and the proposed studies for learning more about Nuralgan 500 mg/200 mg film-coated tablets' 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 minimize its risks.

Together, these measures constitute routine risk minimization 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 Nuralgan 500 mg/200 mg film-coated tablets are risks that need special risk management activities to further investigate or minimize 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 Nuralgan 500 mg/200 mg film-coated tablets. 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 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 Nuralgan 500 mg/200 mg film-coated tablets.

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

There are no studies required for Nuralgan 500 mg/200 mg film-coated tablets.