Part VI: Summary of the risk management plan

Summary of risk management plan for Safinamide 50 mg and 100 mg film-coated tablets (Safinamide)

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

Safinamide Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Safinamide should be used.

Important new concerns or changes to the current ones will be included in updates of this Safinamide RMP.

I. The medicine and what it is used for

Safinamide is authorised for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients.

The tablets contain Safinamide as the active substance and are given by oral route of administration.

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

Important risks of Safinamide, together with measures to minimise such risks and the proposed studies for learning more about Safinamide 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 the tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Safinamide 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 Safinamide. 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	• Dyskinesia • Teratogenicity
Important potential risks	• Retinal degeneration in patients with Parkinson disease treated with safinamide • Use in severe hepatic impairment • Impulse control disorders (ICDs) • Concomitant use of MAOIs, serotonergic drugs, and/or pethidine
Missing information	• Use in patients with history and/or presence of retinal disease • Use of safinamide in patients aged<30 years • Long term use >3 years • Whether specific inhibitors of the amidases involved in the metabolism of safinamide to NW-1153, may increase the exposure of safinamide

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to that of 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 Safinamide

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

There are no studies required for Safinamide.