Part VI: Summary of the risk management plan

Summary of risk management plan for Safinamid DOC 50 mg, 100 mg filmdragerade tabletter (Safinamide)

This is a summary of the risk management plan (RMP) for Safinamid DOC 50 mg, 100 mg filmdragerade tabletter [Safinamid DOC]. The RMP details important risks of Safinamid DOC, how these risks can be minimised, and how more information will be obtained about Safinamid DOC's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Safinamid DOC 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.

It contains safinamide 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 Safinamid DOC, together with measures to minimise such risks and the proposed studies for learning more about Safinamid DOC'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 Safinamid DOC is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Safinamid DOC are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal products 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 Safinamid DOC. Potential risks are concerns for which an association with the use of these medicines 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 products that is currently missing and needs to be collected (e.g. on the long-term use of the medicines).

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 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 Safinamid DOC.

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

There are no studies required for Safinamid DOC.