Part VI: Summary of the risk management plan

Summary of risk management plan for Levodopa/Carbidopa/Entacapone Pharmexon (levodopa/carbidopa/entacapone)

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

Levodopa/Carbidopa/Entacapone Pharmexon's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Levodopa/Carbidopa/Entacapone Pharmexon should be used.

Important new concerns or changes to the current ones will be included in updates of Levodopa/Carbidopa/Entacapone Pharmexon's RMP.

I. The medicine and what it is used for

Levodopa/Carbidopa/Entacapone Pharmexon is authorised for the treatment of adult patients with Parkinson’s disease and end-of-dose motor fluctuations not stabilised on levodopa/dopa decarboxylase (DDC) inhibitor treatment. (see SmPC for the full indication).

It contains levodopa/carbidopa/entacapone as the active substance and it is given orally. Film-coated tablets are available in strengths of 50 mg/12.5 mg/200 mg, 75 mg/18,75 mg/200 mg, 100 mg/25 mg/200 mg, 125 mg/31.25 mg/200 mg, 150 mg/37.5 mg/200 mg, 175 mg/43.75 mg/200 mg and 200 mg/50 mg/200 mg.

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

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

II.A List of important risks and missing information

Important risks of Levodopa/Carbidopa/Entacapone Pharmexon 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 Levodopa/Carbidopa/Entacapone Pharmexon. 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	- Rhabdomyolysis - Neuroleptic Malignant Syndrome - Liver and biliary system disorders and liver laboratory abnormalities - Impulse control disorders - Depression with suicidal tendencies - Gastrointestinal haemorrhage - Colitis - Thrombocytopenia - Orthostatic hypotension - Myocardial infarction and other ischaemic heart disease
Important potential risks	- Severe skin and severe allergic reactions - Medication error
Missing information	- Use in 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 Levodopa/Carbidopa/Entacapone Pharmexon.

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

There are no studies required for Levodopa/Carbidopa/Entacapone Pharmexon.