

## Summary of risk management plan for Levodopa/Carbidopa/Entacapone 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 film-coated tablets (levodopa/carbidopa/entacapone)

This is a summary of the Risk Management Plan (RMP) for Levodopa/Carbidopa/Entacapone 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 film-coated tablets. The RMP details important risks of Levodopa/Carbidopa/Entacapone 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 film-coated tablets, how these risks can be minimised, and how more information will be obtained about Levodopa/Carbidopa/Entacapone 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 film-coated tablets' s risks and uncertainties (missing information).

Levodopa/Carbidopa/Entacapone 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 film-coated tablets' Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Levodopa/Carbidopa/Entacapone 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 film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Levodopa/Carbidopa/Entacapone 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 film-coated tablets' RMP.

### **I. The medicine and what it is used for**

Levodopa/Carbidopa/Entacapone 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 film-coated tablets are authorised for the treatment of adult patients with Parkinson's disease and end-of-dose motor fluctuations not stabilised on levodopa/dopa decarboxylase inhibitor treatment (see SmPC for the full indication). They contain levodopa, carbidopa and entacapone as the active substances and they 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 Levodopa/Carbidopa/Entacapone 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 film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Levodopa/Carbidopa/Entacapone 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 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 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***.

## II.A List of important risks and missing information

Important risks of Levodopa/Carbidopa/Entacapone 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 film-coated tablets 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 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 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 Levodopa/Carbidopa/Entacapone 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 film-coated tablets.

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

There are no studies required for Levodopa/Carbidopa/Entacapone 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 film-coated tablets.