Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for Inbrija. The RMP details important risks of Inbrija and the measures to be taken in order to ensure that Inbrija is used as safely as possible.

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

This summary of the RMP for Inbrija should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Inbrija (levodopa inhalation powder) is indicated for the intermittent treatment of episodic motor fluctuations (OFF episodes) in adult patients with Parkinson's disease (PD) treated with dopa-decarboxylase inhibitor/levodopa.

Further information about the evaluation of Inbrija's benefits can be found in Inbrija's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/inbrija.

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

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

II.A List of important risks and missing information

Important risks of Inbrija 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 Inbrija. 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	• Bronchospasm in patients with lung disease
Missing information	• Use in patients with asthma, COPD, or other chronic underlying lung diseases

II.B Summary of important risks

Important potential risk: Bronchospasm in patients with lung disease	
Evidence for linking the risk to the medicine	There was a potential safety signal in non-PD subjects with asthma experiencing asymptomatic acute decreases in FEV1, but the clinical significance in the PD population is not clear because subjects with ongoing asthma were excluded from studies in PD subjects. Declines in FEV_1 described above in asthma patients without PD were reversible and did not require rescue treatment. Other than cough, the changes in spirometry parameters were not accompanied by any AEs associated with bronchospasm. In clinical trials in PD patients the acute and chronic pulmonary safety evaluations showed no notable differences between treatment with Inbrija compared to a placebo or observational control in spirometry parameters and DLco. Evaluations of vital signs, clinical laboratory, and ECG showed no apparent safety signals. There was no evidence of acute pulmonary effects in smokers.
Risk factors and risk groups	PD patients with asthma, COPD, or other chronic underlying lung diseases may be at risk for bronchospasm. The safety of Inbrija has not been established in these patients.

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 2 Legal status (prescription only medicine) Additional risk minimisation measures: None
Missing information: Use in patients with asthma, COPD, or other chronic underlying lung diseases	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 2 Legal status (prescription only medicine) Additional risk minimisation measures: None

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 Inbrija.

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

There are no studies required for Inbrija.