

## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets (Midodrine hydrochloride)**

This is a summary of the risk management plan (RMP) for Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets. The RMP details important risks of Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets and how more information will be obtained about Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets' risks and uncertainties (missing information).

Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets' RMP.

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

Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets is authorised for: the treatment of severe orthostatic hypotension due to dysfunction of the autonomic nervous system in adults when corrective factors have been ruled out (see SmPC for the full indication).

It contains midodrine hydrochloride as the active substance, and it is given by oral route.

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

Important risks of Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets, together with measures to minimise such 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 Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets is not yet available, it is listed under ‘missing information’ below.

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

Important risks of Midodrine Medical Valley 2.5 mg and 5 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 Midodrine Medical Valley 2.5 mg and 5 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	<ul style="list-style-type: none"><li>• Supine hypertension and/or excessive hypertension upon concomitant use of sympathomimetic and other vasoconstrictive agents.</li><li>• Reflex bradycardia</li></ul>
Important potential risks	None
Missing information	<ul style="list-style-type: none"><li>• Use in patients with hepatic impairment</li></ul>

**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 Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets.

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

There are no studies required for Midodrine Medical Valley 2.5 mg and 5 mg film-coated tablets.