

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

### **Summary of risk management plan for Candesartan cilexetil 2, 4, 8, 16 and 32 mg tablets (Candesartan)**

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

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

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

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

Candesartan Medical Valley 2mg tablets is authorised for the:

- Treatment of primary hypertension in adults
- Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction  $\leq$  40%) when ACE inhibitors are not tolerated, or as adjunctive therapy to ACE inhibitors in patients with symptomatic heart failure despite optimal therapy when mineralocorticoid receptor antagonists are not tolerated

Candesartan Medical Valley 4, 8, 16 and 32 mg tablets is authorised for the:

- Treatment of primary hypertension in adults.
- Treatment of hypertension in children and adolescents aged 6 to <18 years.

Treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction  $\leq$  40%) when ACE inhibitors are not tolerated, or as adjunctive therapy to ACE inhibitors in patients with symptomatic heart failure despite optimal therapy when mineralocorticoid receptor antagonists are not tolerated

It contains Candesartan 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 Candesartan Medical Valley 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*.

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

Important risks of Candesartan Medical Valley 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 Candesartan Medical Valley. 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).

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Foetal toxicity</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• The potential to interfere with heart growth when used long term by children that have not completed their somatic growth</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• None</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 Candesartan Medical Valley.

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

There are no studies required for Candesartan Medical Valley.