Part VI: Summary of the risk management plan

Summary of risk management plan for Candesartan Reddy (candesartan)

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

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

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

I. The medicine and what it is used for

Candesartan Reddy is authorised for following indication:

The treatment of primary hypertension in adults.

The treatment of hypertension in children and adolescents aged 6 to <18 years.

The treatment of adult patients with heart failure and impaired left ventricular systolic function (left ventricular ejection fraction ≤ 40%)

- when Angiotensin Converting Enzyme (ACE)- inhibitors are not tolerated or as add-on therapy to ACE-inhibitors in patients with symptomatic heart failure, despite optimal therapy,
- when mineralocorticoid receptor antagonists are not tolerated (see sections 4.2, 4.4, 4.5 and 5.1) (see SmPC for the full indication).

It contains Candesartan as the active substance and it is given by oral route Candesartan Reddy 4,8,16 and 32 mg Tablets.

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

Important risks of Candesartan Reddy, together with measures to minimise such risks and the proposed studies for learning more about Candesartan Reddy'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 the case of Candesartan Reddy, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment 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 Reddy 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 Reddy. 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	Foetal toxicity
Important potential risks	The potential to interfere with heart growth when used long term by children that have not completed their somatic growth
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 Candesartan Reddy.

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

There are no studies required for Candesartan Reddy.