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 Liconsa. The RMP details important risks of Candesartan Liconsa and how these risks can be minimised, and how more information will be obtained about Candesartan Liconsa's risks and uncertainties (missing information).

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

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

I. The medicine and what it is used for

Candesartan Liconsa 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 ≤ 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 Liconsa 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 ≤ 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 Liconsa 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 Liconsa 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 Liconsa. 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 Liconsa.

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

There are no studies required for Candesartan Liconsa.