Part VI: Summary of the risk management plan

Summary of risk management plan for Enalapril/Lercanidipine STADA (enalapril/lercanidipine)

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

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

I. The medicine and what it is used for

Enalapril/Lercanidipine STADA is authorised for the treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled with enalapril 20 mg and lercanidipine 20 mg given concurrently as separate tablets (see SmPC for the full indication). It contains enalapril/lercanidipine as the active substances and it is given orally.

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

Important risks of Enalapril/Lercanidipine STADA, together with measures to minimise such risks and the proposed studies for learning more about Enalapril/Lercanidipine STADA'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.

If important information that may affect the safe use of Enalapril/Lercanidipine STADA is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Enalapril/Lercanidipine STADA 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 Enalapril/Lercanidipine STADA. 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	• Hypersensitivity reactions, including angioedema • Hyperkalaemia • Hypotension • Dual blockade of the renin-angiotensin-aldosterone system (RAAS) • Hepatic impairment • Use in patients with renal impairment • Drug interactions • Foetotoxicity (with use in 2nd or 3rd trimester of pregnancy)
Important potential risks	• Teratogenicity (with use during 1st trimester of pregnancy) • Increased cardiovascular risk in patient with left ventricular dysfunction and ischaemic heart disease
Missing information	• Use in paediatric patients • Use during breastfeeding • Use in patients with left ventricular outflow obstruction, untreated congestive heart failure, unstable angina pectoris and within one month of a myocardial infarction

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 Enalapril/Lercanidipine STADA.

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

There are no studies required for Enalapril/Lercanidipine STADA.