Part VI: Summary of the risk management plan

Summary of risk management plan for Losartan/ Hydrochlorothiazide STADA 50 mg/12,5 mg, 100 mg/12,5 mg, 100 mg/25 mg film-coated tablets (Losartan, hydrochlorothiazide)

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

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

Important new concerns or changes to the current ones will be included in updates of Losartan/ Hydrochlorothiazide STADA's RMP.

I. The medicine and what it is used for

Losartan/ Hydrochlorothiazide STADA is indicated for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on losartan or hydrochlorothiazide alone (see SmPC for the full indication). It contains losartan and hydrochlorothiazide 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 Losartan/ Hydrochlorothiazide STADA, together with measures to minimise such risks and the proposed studies for learning more about Losartan/ Hydrochlorothiazide 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.

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 Losartan/ Hydrochlorothiazide 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 Losartan/ Hydrochlorothiazide 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	• None
Important potential risks	• None
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 Losartan/ Hydrochlorothiazide STADA.

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

There are no studies required for Losartan/ Hydrochlorothiazide STADA.