

Part VI: Summary of the risk management plan

Summary of risk management plan for Losartan Medical Valley, Losartankalium Liconsa and Lotanec (losartan)

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

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

Important new concerns or changes to the current ones will be included in updates Losartan Medical Valley, Losartankalium Liconsa and Lotanec's RMP.

I. The medicine and what it is used for

Losartan Medical Valley, Losartankalium Liconsa and Lotanec is authorised for:

- Treatment of essential hypertension in adults and in children and adolescents 6 – 18 years of age
- Treatment of renal disease in adult patients with hypertension and type 2 diabetes mellitus with proteinuria ≥ 0.5 g/day as part of an antihypertensive treatment
- Treatment of chronic heart failure in adult patients, when treatment with Angiotensin-converting enzyme (ACE) inhibitors is not considered suitable due to incompatibility, especially cough, or contraindication
- Reduction in the risk of stroke in adult hypertensive patients with left ventricular hypertrophy documented by ECG (see SmPC for the full indication)

It contains losartan potassium as the active substance, and it is given by the oral route.

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

Important risks of Losartan Medical Valley, Losartankalium Liconsa and Lotanec, 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, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Losartan Medical Valley, Losartankalium Liconsa and Lotanec is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Losartan Medical Valley, Losartankalium Liconsa and Lotanec 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 Medical Valley, Losartankalium Liconsa and Lotanec. 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	<ul style="list-style-type: none">• None
Important potential risks	<ul style="list-style-type: none">• None
Missing information	<ul style="list-style-type: none">• None

II.B Summary of important risks

The safety information in the 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 Medical Valley, Losartankalium Liconsa and Lotanec.

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

There are no studies required for Losartan Medical Valley Losartan Medical Valley, Losartankalium Liconsa and Lotanec.