Summary of risk management plan for Losarion 50 mg and 100 mg film coated tablets (Losartan potassium) Orion Corporation

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This is a summary of the risk management plan (RMP) for Losarion 50 Mg and 100 mg Film-Coated Tablets. The RMP details important risks of Losarion 50 Mg and 100 mg Film-Coated Tablets, how these risks can be minimised, and how more information will be obtained about Losarion 50 Mg and 100 mg Film-Coated Tablets risks and uncertainties (missing information).

Losarion 50 Mg and 100 mg Film-Coated Tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Losarion 50 Mg and 100 mg Film-Coated Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Losarion 50 Mg and 100 mg Film-Coated Tablets RMP.

I. The medicine and what it is used for

Losartan is used:

- to treat patients with high blood pressure in adults and in children and adolescents 6-18 years of age.
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0.5g per day.
- to treat patients with chronic heart failure when therapy with ACE inhibitors is not considered suitable.
- to decrease the risk of stroke ("LIFE indication") in patients with high blood pressure and a thickening of the left ventricle (see SmPC for the full indication).

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

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

Important risks of Losartan, together with measures to minimise such risks and the proposed studies for learning more about Losartan'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 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 potassium. 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 identified 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

There are no studies required for Losartan