Part VI: Summary of the risk management plan

Summary of risk management plan for Furosemid Omet Pharma 20 and 40 mg tablets

This is a summary of the risk management plan (RMP) for Furosemid Omet Pharma 20 and 40 mg tablets.

Furosemid Omet Pharma summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Furosemid Omet Pharma 20 and 40 mg tablets should be used.

I. The medicine and what it is used for

Furosemide is indicated for treatment of oedema (associated with cardiac disease, liver disease, renal disease, pulmonary oedema) and arterial hypertension.

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

Important risks of Furosemid Omet Pharma film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Furosemid Omet Pharma'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

Summary of safety concerns	
Important identified risks	None
Important potential risks	None

Summary of safety concerns	
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

Not applicable.

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

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

Not applicable.