Summary of risk management plan for Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard (sunitinib)

This is a summary of the risk management plan (RMP) for Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard. The RMP details important risks of Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard, how these risks can be minimised, and how more information will be obtained about Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard 's risks and uncertainties (missing information).

Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard should be used.

I. The medicine and what it is used for

Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard is authorised for treatment of Gastrointestinal stromal tumour, Metastatic renal cell carcinoma and Pancreatic neuroendocrine tumours (see SmPC for the full indication). It contains sunitinib as the active substance and it is given by oral administration.

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

Important risks of Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard, together with measures to minimise such risks and the proposed studies for learning more about Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard '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 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 Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard 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 Sunitinib Medical Valley 12,5 mg, 25 mg, 37,5 mg, 50 mg capsules, hard. 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	• Cardiotoxicity ➢ Torsade de pointes ➢ Left ventricular dysfunction/Heart failure ➢ Pericardial events ➢ Cardiac ischemic events • Reversible Posterior Leukoencephalopathy Syndrome • Hepatic failure • Osteonecrosis of the jaw • Severe cutaneous adverse • Renal failure
Important potential risks	• Carcinogenicity
Missing information	• Severe hepatic impairment

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

Not applicable.