

Part VI: Summary of the risk management plan

Summary of risk management plan for Sunitinib 12.5 mg, 25 mg, 37.5 and 50 mg Capsules, Hard (Sunitinib).

This is a summary of the risk management plan (RMP) for Sunitinib 12.5 mg, 25 mg, 37.5 and 50 mg capsules, hard (hereinafter referred to as Sunitinib). The RMP details important risks of sunitinib, how these risks can be minimised, and how more information will be obtained about sunitinib's risks and uncertainties (missing information).

Sunitinib summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how sunitinib should be used.

Important new concerns or changes to the current ones will be included in updates of sunitinib's RMP.

I. The medicine and what it is used for

Gastrointestinal stromal tumour (GIST)

Sunitinib is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.

Metastatic renal cell carcinoma (MRCC)

Sunitinib is indicated for the treatment of advanced/metastatic renal cell carcinoma (MRCC) in adults.

Pancreatic neuroendocrine tumours (pNET)

Sunitinib is indicated for the treatment of unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults

(See SmPC for the full indication). It contains sunitinib as the active substance and is given orally.

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

Important risks of sunitinib together with measures to minimise such risks and the proposed studies for learning more about sunitinib'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 to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the public (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 the adverse reactions is collected continuously and regularly analysed, 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 is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of sunitinib are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by the patient. 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. 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 reactions
	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

There are no studies which are conditions of the marketing authorisation or specific obligation of sunitinib.

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

There are no studies required for sunitinib.