7 Part VI: Summary of the risk management plan (RMP) Sunitinib, 12.5 mg, 25 mg, 37.5 mg and 50 mg, Hard capsules

This is a summary of the RMP for sunitinib hard capsule. The RMP details important risks of sunitinib hard capsule, how these risks can be minimized, and how more information will be obtained about sunitinib hard capsule's risks and uncertainties (missing information).

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

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

7.1 Part VI: I. The medicine and what it is used for

Sunitinib hard capsule is authorized for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumor (GIST) in adults after failure of imatinib treatment due to resistance or intolerance, or for advanced/metastatic renal cell carcinoma (MRCC) in adults, or unresectable or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) with disease progression in adults. It contains sunitinib malate as the active substance and it is given orally, in the form of 12.5 mg, 25 mg, 37.5 mg and 50 mg, hard capsules.

7.2 Part VI: II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of sunitinib hard capsule, with measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment (if available) 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 hard capsule is not yet available, it is listed under 'missing information' below.

7.2.1 Part VI – II.A: List of important risks and missing information

Important risks of sunitinib hard capsule are risks that need special risk management activities to further investigate or minimize 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 hard capsules. 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).

Important identified risks	Hypertension
	Hemorrhagic events
	Cytopenic events
	Cardiotoxicity - Torsade de pointes - Left ventricular dysfunction/Heart failure - Pericardial events - Cardiac ischemic events
	Fatigue and asthenia
	Thyroid dysfunction
	Serious infection - Necrotizing fasciitis
	Thrombotic microangiopathy
	Proteinuria/nephrotic syndrome
	Reversible Posterior Leukoencephalopathy Syndrome
	Fistula formation
	Hepatic failure
	Embolic and thrombotic/embolism and thrombosis
	Gastrointestinal perforation
	Pancreatitis
	Myopathy/rhabdomyolysis
	Osteonecrosis of the jaw
	Esophagitis
	Toxic epidermal necrolysis, Stevens-Johnson Syndrome, erythema multiforme
	Renal failure
	Adrenal gland dysfunction
	Cholecystitis
	Tumor lysis syndrome
	Angioedema
	Hypoglycemia
Important potential risks	Carcinogenicity
	Other potential cardiac effects - Conduction defect events - Tachycardia events Retinal detachment
	Retinal detatchment
	Reproductive and developmental toxicity
Identified and potential interactions	Drug interaction with CYP3A4 inhibitor or inducer
Missing information	Pediatric patients
	Severe hepatic impairment
	Cardiac impairment

7.2.2 Part VI – II.B: Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

7.2.3 Part VI – II.C: Post-authorization development plan

7.2.3.1 II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of sunitinib hard capsule.

7.2.3.2. II.C.2. Other studies in post-authorization development plan