Part VI: Summary of the risk management plan

Summary of risk management plan for Sunitinib Accord 12.5/25/37.5/50 mg hard capsules (Sunitinib)

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

Sunitinib Accord 12.5/25/37.5/50 mg hard capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sunitinib Accord 12.5/25/37.5/50 mg hard capsules should be used.

This summary of the RMP for Sunitinib Accord 12.5/25/37.5/50 mg hard capsules should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Sunitinib Accord 12.5/25/37.5/50 mg hard capsules RMP.

I. The medicine and what it is used for

Sunitinib Accord 12.5 mg/ 25 mg/ 37.5 mg and 50 mg hard capsules are indicated for following indications:

Gastrointestinal stromal tumour (GIST)

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

Pancreatic neuroendocrine tumours (pNET)

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

It contains Sunitinib as the active substance and it is given orally.

Further information about the evaluation of Sunitinib Accord 12.5/25/37.5/50 mg hard capsule's benefits can be found in Sunitinib Accord 12.5/25/37.5/50 mg hard capsule's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

https://www.ema.europa.eu/en/medicines/human/EPAR/sunitinib-accord

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

Important risks of Sunitinib Accord 12.5/25/37.5/50 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Sunitinib Accord 12.5/25/37.5/50 mg hard capsules 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 including signal management activity, 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 Accord 12.5/25/37.5/50 mg hard capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Sunitinib Accord 12.5/25/37.5/50 mg hard capsules 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 Accord 12.5/25/37.5/50 mg 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	• 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
	  • Toxic epidermal necrolysis
	  • Stevens-Johnson Syndrome
	  • Erythema multiforme
	• 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 authorization or specific obligation of Sunitinib Accord 12.5/25/37.5/50 mg hard capsules.

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

There are no studies required for Sunitinib Accord 12.5/25/37.5/50 mg hard capsules as post-authorisation development plan.