13 Part VI: Summary of the risk management plan for Sorafenib, 200 mg and 400 mg, Film-coated tablets

This is a summary of the risk management plan (RMP) for Sorafenib, 200 mg and 400 mg, Film-coated tablets. The RMP details important risks of Sorafenib, Film-coated tablets, how these risks can be minimized, and how more information will be obtained about Sorafenib, Film-coated tablets' risks and uncertainties (missing information).

Sorafenib, Film-coated tablets' summaries of product characteristics (SmPCs) and its package leaflets (PLs) give essential information to healthcare professionals (HCPs) and patients on how Sorafenib, film-coated tablet should be used.

Important new concerns or changes to the current ones will be included in updates of the Sorafenib, Film-coated tablets' RMP.

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

Sorafenib, Film-coated tablets are authorized for:

Hepatocellular carcinoma (HCC)
Sorafenib is indicated for the treatment of HCC

Renal cell carcinoma (RCC)
Sorafenib is indicated for the treatment of patients with advanced RCC who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy.

It contains Sorafenib as active substance and is taken orally as 200 mg and 400 mg, Film-coated tablets.

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

Important risks of Sorafenib, Film-coated tablets, together with measures to minimize such risks and the proposed studies for learning more about Sorafenib, Film-coated tablet's 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 PLs and SmPCs 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 Reports (PSURs) assessment (if

applicable) so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities.*

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

Important risks of Sorafenib, Film-coated tablets 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 Sorafenib, Film-coated tablets. 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).

Table 13-1 List of important risks and missing information

List of important risks and missing information	
Important identified risks	Severe skin adverse events
	Reversible posterior leukoencephaopathy syndrome (RPLS)
	Hemorrhage including lung hemorrhage, gastrointestinal hemorrhage (GI) and cerebral hemorrhage
	Arterial thrombosis (myocardial infarction)
	Congestive heart failure (CHF)
	Squamous cell cancer of the skin
	GI perforation
	Renal dysfunction
	Interstitial lung disease (ILD)-like events
	Drug-induced hepatitis
Important potential risks	Arterial thrombosis (Cerebral Ischemia)
	Wound healing complications
	Microangiopathy
	Torsade De Pointes
	Pregnancy and exposure through breastfeeding
Missing Information	None

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

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

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

13.2.3.1 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 Sorafenib, Film-coated tablets.