Summary of risk management plan for Sorafenib Accord 200 mg film-coated tablets (Sorafenib)

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

Sorafenib Accord 200 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Sorafenib Accord 200 mg film-coated tablets should be used.

This summary of the RMP for Sorafenib Accord 200 mg film-coated tablets 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 Sorafenib Accord 200 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Sorafenib Accord is indicated for following indications:

Hepatocellular carcinoma

Sorafenib Accord is indicated for the treatment of hepatocellular carcinoma.

Renal cell carcinoma

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

It contains sorafenib as the active substance and it is given by oral route.

Further information about the evaluation of Sorafenib Accord 200 mg film-coated tablets' benefits can be found in Sorafenib Accord 200 mg film-coated tablets' 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/sorafenib-accord.

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

Important risks of Sorafenib Accord 200 mg film-coated tablets together with measures to minimise such risks and the proposed studies for learning more about Sorafenib Accord 200 mg film-coated tablets' 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 during signal management activity, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Sorafenib Accord 200 mg film-coated tablets 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 Sorafenib Accord 200 mg 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).

Important identified risks	• Severe skin adverse events • Reversible posterior leukoencephalopathy syndrome (RPLS)

	• Hemorrhage including lung hemorrhage, gastroinestinal (GI) hemorrhage and cerebral hemorrhage • Arterial thrombosis (myocardial infarction) • Congestive heart failure (CHF) • Squamous cell cancer of the skin • Gastrointestinal 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 (TdP) • Pregnancy and exposure through breastfeeding
Missing information	• None

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 Sorafenib Accord 200 mg film-coated tablets.

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

There are no studies required for Sorafenib Accord 200 mg film-coated tablets.