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## **Part VI: Summary of the risk management plan**

### **Summary of risk management plan for Axitinib STADA 1 mg, 3 mg, 5 mg, and 7 mg film-coated tablets**

This is a summary of the risk management plan (RMP) for Axitinib. The RMP details important risks of Axitinib, how these risks can be minimised, and how more information will be obtained about Axitinib's risks and uncertainties (missing information).

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

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

#### **I. The medicine and what it is used for**

Axitinib is authorised for the treatment of adult patients with advanced renal cell carcinoma after failure of prior treatment with sunitinib or a cytokine. It contains axitinib as the active substance and it is given by oral route of administration.

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

Important risks of Axitinib, together with measures to minimise such risks and the proposed studies for learning more about Axitinib'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 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, 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 Axitinib is not yet available, it is listed under ‘missing information’ below.

### ***II.A List of important risks and missing information***

Important risks of Axitinib 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 Axitinib. 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).

<b>List of important risks and missing information</b>	
Important identified risks	Arterial embolic and thrombotic events
	Congestive heart failure/cardiomyopathy
	Effects on the exocrine pancreas
	Gastrointestinal perforation and fistula
	<i>Haemorrhage</i>
	<i>Posterior reversible encephalopathy syndrome</i>
	Renal failure
Important potential risks	Venous embolic and thrombotic events
	Carcinogenicity
	<i>Osteonecrosis of jaw</i>
	Reproductive and developmental toxicity
Missing information	<i>Torsade de pointes</i> due to QT prolongation
	Risks in paediatric subjects
	Risks in pregnant and lactating women
	Risks in subjects with a recent major surgery (within 4 weeks) or radiation therapy (within 2 weeks)
	Risks in subjects with active peptic ulcer disease
	Risks in subjects with brain metastasis, spinal cord compression, or carcinomatous meningitis
	Risks in subjects with moderate and severe renal impairment (serum creatinine >1.5 times the ULN or calculated creatinine clearance <60 mL/min)
Risks in subjects with severe hepatic impairment (Child-Pugh Class C)	

ULN = Upper Limit of Normal

### ***II.B Summary of important risks***

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

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*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 Axitinib.

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

There are no studies required for Axitinib.