Souhrn plánu řízení rizik podle § 99 odst. 8 písm. a) zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů (1)

Pazopanib Pharmagen potahované tablety 200 mg

Pazopanib Pharmagen potahované tablety 400 mg

Administrativní informace:

Léčivá látka/látky	Pazopanib-hydrochlorid
Léková forma/formy	Potahované tablety
Síla/síly	200 mg, 400 mg
Držitel rozhodnutí o registraci	Pharmagen CZ, s.r.o. Praha
Registrační číslo/čísla	44/547/22-C 44/548/22-C
Verze a datum plánu řízení rizik	Verze 1.0, 24.6.2025

Následující výňatek z plánu řízení rizik (RMP) výše uvedeného léčivého přípravku/léčivých přípravků je souhrnem podstatných informací uvedených ve zmíněném RMP. RMP popisuje opatření, která mají být přijata, aby bylo zajištěno, že tento léčivý přípravek/tyto léčivé přípravky budou používány co nejbezpečněji. Souhrn RMP je potřeba číst spolu se schváleným souhrnem údajů o přípravku/přípravcích a příbalovou informací.

Tento souhrn RMP připravil Státní ústav pro kontrolu léčiv za účelem splnění své zákonné povinnosti týkající se transparentnosti vůči veřejnosti.

1) Zákon č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů

Summary of risk management plan for Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets (pazopanib)

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

Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets.

I. The medicine and what it is used for

Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets are indicated to treat:

- Renal cell carcinoma (RCC);

- Soft-tissue sarcoma (STS).

Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets contain pazopanib as the active substance and they are intended for oral use.

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

Important risks of Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets together with measures to minimise such risks and the proposed studies for learning more about Pazopanib Pharmagen 200 mg and 400 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, 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 Pazopanib Pharmagen 200 mg and 400 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 Pazopanib Pharmagen 200 mg and 400 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);

Summary of safety concerns	
Important identified risks	• Hepatic dysfunction • Cardiac arrhythmias • Hypertension • Hypothyroidism • Cardiac dysfunction • Posterior reversible encephalopathy syndrome (PRES)
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

Safety concern	**Risk minimisation measures**	**Pharmacovigilance activities**
Important Identified Risks		
Hepatic dysfunction	Routine risk communication: SmPC sections 4.2, 4.4 and 4.8 PL sections 2 Routine risk minimisation activities recommending specific clinical measures to address the risk: Liver function should be monitored in SmPC section 4.4 Dose modification for elevated liver test values in SmPC Table 1 What you need to know in PL section 2	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: None Additional pharmacovigilance activities: None

Safety concern	Risk minimisation measures	Pharmacovigilance activities
	Other routine risk minimisation measures beyond the Product Information: None Legal status: By medical prescription only Additional risk minimisation measures: None	
Cardiac arrhythmias	Routine risk communication: SmPC sections 4.4 and 4.8 PL sections 2 and 4 Routine risk minimisation activities recommending specific clinical measures to address the risk: Pazopanib should be used with caution in SmPC section 4.4 ECG monitoring and electrolytes should be maintained within normal range in SmPC section 4.4 What you need to know in PL section 2 and 4 Other routine risk minimisation measures beyond the Product Information: None Legal status: By medical prescription only Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: None Additional pharmacovigilance activities: None
Hypertension	Routine risk communication: SmPC sections 4.4, 4.8 and 4.9 PL sections 2 and 4 Routine risk minimisation activities recommending specific clinical measures to address the risk:	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: None Additional pharmacovigilance activities: None

Safety concern	Risk minimisation measures	Pharmacovigilance activities
	Blood pressure should be well controlled in SmPC section 4.4 Hypertension should be monitored early and frequently after starting pazopanib in SmPC section 4.4 Dose interruption/reduction combined with antihypertensives in SmPC section 4.4 Dose discontinuation if hypertensive crisis in SmPC section 4.4 What you need to know in PL section 2 and 4 Other routine risk minimisation measures beyond the Product Information: None Legal status: By medical prescription only Additional risk minimisation measures: None	
Hypothyroidism	Routine risk communication: SmPC sections 4.4 and 4.8 PL sections 4 Routine risk minimisation activities recommending specific clinical measures to address the risk: Thyroid function test should be performed at baseline and periodically after starting pazopanib in SmPC section 4.4 What you need to know in PL section 4 Other routine risk minimisation measures beyond the Product Information: None Legal status: By medical prescription only	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: None Additional pharmacovigilance activities: None

Safety concern	Risk minimisation measures	Pharmacovigilance activities
	Additional risk minimisation measures: None	
Cardiac dysfunction	Routine risk communication: SmPC sections 4.4 and 4.8 PL sections 4 Routine risk minimisation activities recommending specific clinical measures to address the risk: Concurrent hypertension may exacerbate cardiac dysfunction, increasing cardiac afterload; prior anthracycline therapy in SmPC section 4.4 Carefully monitor fee signs and symptoms of CHF; baseline and periodic LVEF evaluations are recommended in section 4.4 What you need to know in PL section 4 Other routine risk minimisation measures beyond the Product Information: None Legal status: By medical prescription only Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Specific adverse drug reaction checklist Additional pharmacovigilance activities: None
Posterior reversible encephalopathy syndrome (PRES)	Routine risk communication: SmPC sections 4.4 and 4.8 PL sections 4 Routine risk minimisation activities recommending specific clinical measures to address the risk: PRES can present with headache, hypertension, seizure, lethargy, confusion, blindness, and other visual and neurological disturbances in section 4.4	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: None Additional pharmacovigilance activities: None

Safety concern	Risk minimisation measures	Pharmacovigilance activities
	What you need to know in PL section 4 Other routine risk minimisation measures beyond the Product Information: None Legal status: By medical prescription only Additional risk minimisation measures: None	

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 Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets.

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

There are no studies required for Pazopanib Pharmagen 200 mg and 400 mg film-coated tablets.