

PAZOBRITE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for PAZOBRITE (Pazopanib tablet)

[Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Pazopanib is an orally administered, potent multi-target tyrosine kinase inhibitor (TKI) of vascular endothelial growth factor receptors (VEGFR) -1, -2, and -3, platelet-derived growth factor (PDGFR) - α and - β , and stem cell factor receptor (c-KIT), with IC50 values of 10, 30, 47, 71, 84 and 74 nM, respectively. In preclinical experiments, pazopanib dose-dependently inhibited ligand-induced auto-phosphorylation of VEGFR-2, c-Kit and PDGFR- β receptors in cells. In vivo, pazopanib inhibited VEGF-induced VEGFR-2 phosphorylation in mouse lungs, angiogenesis in various animal models, and the growth of multiple human tumour xenografts in mice.

INDICATIONS: It is indicated for the treatment of patients with advanced renal cell carcinoma and for the treatment of patients with advanced Soft Tissue Sarcoma (STS) who have received prior chemotherapy.

DOSAGE AND ADMINISTRATION: The Daily recommended dose is as directed by the physician. Pazopanib is for oral use. It should be taken without food, at least one hour before or two hours after a meal.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients.

WARNINGS & PRECAUTIONS: If you have heart disease, liver disease, heart failure or a heart attack, prior collapse of a lung, problems with bleeding, blood clots or narrowing of the arteries stomach or bowel problems such as perforation (hole) or fistula (abnormal passages forming between parts of the intestine), thyroid problems, problems with your kidney function or if you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall. You may need extra tests to check that your kidneys, heart and liver are working properly. Pazobrite can raise your blood pressure. Your blood pressure will be checked before you take pazobrite and while you are taking it. If you have high blood pressure you will be treated with medicines to reduce it. If you are having operation or surgery, stop Pazobrite at least 7 days before your operation as it may affect wound healing. Your treatment will be restarted when the wound has adequately healed. Pazobrite can make some conditions worse or cause serious side effects. You must look out for certain symptoms while you are taking Pazobrite to reduce the risk of any problems.

DRUG INTERACTIONS:

Some medicines may affect how Pazobrite works or make it more likely that you'll have side effects. Pazobrite can also affect how some other medicines work. These include: clarithromycin, ketoconazole, itraconazole, rifamicin, telithromycin, voriconazole (used to treat infection), atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV), nefazodone (used to treat depression), simvastatin and possibly other statins (used to treat high cholesterol levels), medicines that reduce stomach acid. The type of medicine that you are taking to reduce your stomach acid (e.g. proton pump inhibitor, H2 antagonists or antacids) may affect how Pazobrite is taken. Don't take Pazobrite with food, as it affects the way the medicine is absorbed. Take it at least two hours after a meal or one hour before a meal. Do not drink grapefruit juice while you are being treated with Pazobrite as this may increase the chance of side effects.

ADVERSE REACTIONS: Side effects listed below have been reported in the following frequencies.

Very common: High blood pressure, Diarrhoea, Feeling or being sick (nausea or vomiting), Stomach pain, Loss of appetite, Weight loss, Taste disturbance or loss of taste, Sore mouth, Headache, Tumour pain, Lack of energy, feeling weak or tired, Changes in hair colour, Unusual hair loss or thinning, Loss of skin pigment, Skin rash, possibly involving peeling of the skin, Redness and swelling of the palms of the hands or soles of the feet. *Common:* Indigestion, bloating, nose bleeding, Difficult sleeping, Dry mouth, Abnormal drowsiness - underactive thyroid gland, abnormal liver function, increase in bilirubin (a substance produced by the liver), increase in lipase (an enzyme involved in digestion, increase in creatinine (a substance produced in muscles), changes in the levels of other different chemicals / enzymes in the blood. Your doctor will inform you of the results of the blood tests. *Uncommon:* stroke, sudden shortness of breath, heart rhythm disturbance, blood clots, and pancreatitis, hole (perforation) in stomach or intestine, temporary fall in blood supply to the brain and heavy or irregular menstrual periods. *Not known:* An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections), tumour lysis syndrome resulting from a fast breakdown of cancer cells and liver failure. *Rare side effects:* Inflammation of the lung (pneumonitis).

MARKETED BY:



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(Additional information is available on request)