Pazotab™

Pazopanib Hydrochloride INN Film Coated Tablet

DESCRIPTION

Pazotab™ is a preparation of Pazopanib Hydrochloride. Pazopanib is a multi-tyrosine kinase inhibitor of vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2, VEGFR-3, platelet-derived growth factor receptor (PDGFR)-α and -β, fibroblast growth factor receptor (FGFR) -1 and -3, cytokine receptor (Kit), interleukin-2 receptor inducible T-cell kinase (Itk), Leukocyte-specific protein tyrosine kinase (Lck), and transmembrane glycoprotein receptor tyrosine kinase (c-Fms). In vitro, Pazopanib inhibited ligand-induced autophosphorylation of VEGFR-2, Kit and PDGFR-β receptors. In vivo, Pazopanib inhibited VEGF-induced VEGFR-2 phosphorylation in mouse lungs, angiogenesis in a mouse model, and the growth of some human tumor xenografts in mice.

INDICATIONS

Pazotab™ is indicated for the treatment of patients with advanced renal cell carcinoma (RCC).

DOSAGE AND ADMINISTRATION

The recommended starting dose of Pazopanib is 800 mg orally once daily without food (at least 1 hour before or 2 hours after a meal). The dose of Pazopanib should not exceed 800 mg. Do not crush tablets due to the potential for increased rate of absorption which may affect systemic exposure. If a dose is missed, it should not be taken if it is less than 12 hours until the next dose.

CONTRAINDICATIONS

None.

SIDE EFFECTS

- Diarrhea, nausea, anorexia, and vomiting
- Hypertension
- Hair color changes (depigmentation)

PRECAUTION AND WARNING

- Increases in serum transaminase levels and bilirubin were observed. Severe and fatal hepatotoxicity has occurred. Measure liver chemistries before the initiation of treatment and regularly during treatment.
- Prolonged QT intervals and torsades de pointes have been observed. Use with caution in patients at higher risk of developing QT interval prolongation. Monitoring electrocardiograms and electrolytes should be considered.
- Fatal hemorrhagic events have been reported. Pazopanib has not been studied in patients who have a history of hemoptysis, cerebral, or clinically significant gastrointestinal hemorrhage in the past 6 months and should not be used in those patients.

DRUG INTERACTIONS

- CYP3A4 Inhibitors: Avoid use of strong CYP3A4 inhibitors. If coadministration is warranted, reduce the dose of Pazopanib to 400 mg.
- CYP3A4 Inducers: Consider an alternate concomitant medication with no or minimal enzyme induction potential or avoid Pazopanib.
- CYP Substrates: Concomitant use of Pazopanib with agents with narrow therapeutic windows that are metabolized by CYP3A4, CYP2D6, or CYP2C8 is not recommended.
- Concomitant use of Pazopanib and simvastatin increases the risk of ALT elevations and should be undertaken with caution and close monitoring.
- Drugs that Raise Gastric pH: Avoid concomitant use of Pazopanib with drugs that raise gastric pH. Consider short-acting antacids in place of proton pump inhibitors (PPIs) and H2 receptor antagonists. Separate antacid and pazopanib dosing by several hours.

USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies of Pazopanib in pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be advised to avoid becoming pregnant while taking Pazopanib.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Pazopanib, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

PHARMACEUTICAL PRECAUTION

Store at or below 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Pazotab™ Tablet: Box containing 7 strips of 4 tablets each. Each tablet contains Pazopanib Hydrochloride INN equivalent to Pazopanib 200 mg.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM0931 V01