

Dasatab™

Dasatinib INN Film Coated Tablet

DESCRIPTION

Dasatab™ is a preparation of Dasatinib. Dasatinib, at nanomolar concentrations, inhibits the following kinases: BCR-ABL, SRC family (SRC, LCK, YES, FYN), c-KIT, EphA2, and PDGFRβ. Based on modeling studies, Dasatinib is predicted to bind to multiple conformations of the ABL kinase.

INDICATIONS

- Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The trial is ongoing and further data will be required to determine long-term outcome.
- Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including Imatinib.
- Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.

DOSAGE AND ADMINISTRATION

- Chronic phase CML: 100 mg once daily.
- Accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL: 140 mg once daily.
- Administered orally, with or without a meal. Tablets should not be crushed or cut.

CONTRAINDICATIONS

None

SIDE EFFECTS

- Myelosuppression
- Fluid retention
- Diarrhea
- Headache
- Musculoskeletal pain
- Rash

PRECAUTION AND WARNING

- Myelosuppression: Severe thrombocytopenia, neutropenia, and anemia may occur and require dose interruption or reduction. Monitor complete blood counts regularly.
- Bleeding Related Events (mostly associated with severe thrombocytopenia): CNS and gastrointestinal hemorrhages, including fatalities have occurred. Severe hemorrhage may require treatment interruptions and transfusions. Use Dasatinib with caution in patients requiring medications that inhibit platelet function or anticoagulants.
- Fluid Retention: Dasatinib is associated with fluid retention, sometimes severe, including ascites, edema, and pleural and pericardial effusions. Manage with appropriate supportive care measures.
- QT Prolongation: Use Dasatinib with caution in patients who have or may develop prolongation of the QT interval.

- Congestive Heart Failure, Left Ventricular Dysfunction and Myocardial Infarction: Monitor patients for signs or symptoms consistent with cardiac dysfunction and treat appropriately.
- Fetal harm may occur when administered to a pregnant woman. Women should be advised of the potential hazard to the fetus and to avoid becoming pregnant.

DRUG INTERACTIONS

- CYP3A4 Inhibitors: May increase Dasatinib drug levels and should be avoided. If co-administration cannot be avoided, monitor closely and consider reducing Dasatinib dose.
- CYP3A4 Inducers: May decrease Dasatinib drug levels. If co-administration cannot be avoided, consider increasing Dasatinib dose.
- Antacids: May decrease Dasatinib drug levels. Avoid simultaneous administration. If needed, administer the antacid at least 2 hours prior to or 2 hours after the dose of Dasatinib.
- H2 Antagonists/Proton Pump Inhibitors: May decrease Dasatinib drug levels. Consider antacids in place of H2 antagonists or proton pump inhibitors.

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. There are no adequate and well-controlled studies of Dasatinib in pregnant women. Women of childbearing potential should be advised to avoid becoming pregnant while receiving treatment with Dasatinib.

It is unknown whether Dasatinib 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 Dasatinib, 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 & wet place. Keep out of reach of children.

PACKAGING

Dasatab™ 20 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Dasatinib INN 20 mg.

Dasatab™ 100 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Dasatinib INN 100 mg.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM1236 V01