Ibrutab™

Ibrutinib INN Film Coated Tablet

DESCRIPTION

Ibrutab™ is a preparation of Ibrutinib. Ibrutinib is a small-molecule inhibitor of Bruton's Tyrosine Kinase (BTK). Ibrutinib forms a covalent bond with a cysteine residue in the BTK active site, leading to inhibition of BTK enzymatic activity. BTK is a signaling molecule of the B-cell antigen receptor (BCR) and cytokine receptor pathways. BTK's role in signaling through the B-cell surface receptors results in activation of pathways necessary for B-cell trafficking, chemotaxis, and adhesion. Nonclinical studies show that Ibrutinib inhibits malignant B-cell proliferation and survival in vivo as well as cell migration and substrate adhesion in vitro.

INDICATIONS

Ibrutinib (**Ibrutab™**) is a kinase inhibitor indicated for the treatment of adult patients with:

- Mantle Cell Lymphoma (MCL) who have received at least one prior therapy. Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.
- Chronic Lymphocytic Leukemia (CLL) who have received at least one prior therapy.
- Chronic lymphocytic leukemia with 17p deletion.
- Waldenstrom's macroglobulinemia (WM)

DOSAGE AND ADMINISTRATION

- MCL: 560 mg taken orally once daily (four 140 mg tablet once daily).
- CLL and WM: 420 mg taken orally once daily (three 140 mg tablets once daily)

Dose should be taken orally once daily at approximately the same time each day. Do not cut, crush or chew the tablets. Only swallow tablets with a glass of water.

CONTRAINDICATIONS

None

SIDE EFFECTS

- Thrombocytopenia, neutropenia, anemia
- Diarrhea, nausea
- Fatigue
- Musculoskeletal pain
- Bruising
- Upper respiratory tract infection
- Rash
- Cardiac failure

PRECAUTION AND WARNING

- Hemorrhage: Monitor for bleeding.
- Infections: Monitor patients for fever and infections and evaluate promptly.
- Cytopenias: Check complete blood counts monthly.
- Atrial Fibrillation: Monitor patients for atrial fibrillation.
- Second Primary Malignancies: Other malignancies have occurred in patients, including skin cancers, and other carcinomas.
- Tumor Lysis Syndrome (TLS): Monitor patients at risk for TLS (e.g. high tumor burden).
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise women of the potential risk to a fetus and to avoid pregnancy while taking the drug.
- Cardiac arrhythmia: Monitor for symptoms of arrhythmias.

DRUG INTERACTIONS

- CYP3A Inhibitors: Avoid co-administration with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, reduce Ibrutinib dose.
- CYP3A Inducers: Avoid co-administration with strong CYP3A inducers.

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. Based on findings in animals, Ibrutinib can cause fetal harm when administered to a pregnant woman. If Ibrutinib is used during pregnancy or if the patient becomes pregnant while taking Ibrutinib, the patient should be apprised of the potential hazard to the fetus.

It is not known whether Ibrutinib 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 Ibrutinib, 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

Ibrutab™ Tablet: Box containing 4 strips of 7 tablets each. Each tablet contains Ibrutinib INN 140 mg.

SK+F ONCOLOGY
Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM1319 V01