



Ibruent™

Ibrutinib 140 mg

Presentation

Ibruent™140: Each capsule contains Ibrutinib INN 140 mg

Description

Ibrutinib is a small-molecule inhibitor of 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 and Uses

Ibrutinib, is a kinase inhibitor indicated for the treatment of 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
- Waldenström's macroglobulinemia (WM)

Dosage and Administrations

MCL: 560 mg taken orally once daily (four 140 mg capsules once daily)

CLL and WM: 420 mg taken orally once daily (three 140 mg capsules once daily)

Capsules should be taken orally with a glass of water. The capsules should not be opened, broke, or chewed

Side-effects

The most common adverse reactions (≥25%) in patients with B-cell malignancies (MCL, CLL, WM) were thrombocytopenia, neutropenia, diarrhea, anemia, fatigue, musculoskeletal pain, bruising, nausea, upper respiratory tract infection, and rash.

Contraindications

None

Precautions

- Hemorrhage: Should be monitored for bleeding
- Infections: Patients should be monitored for fever and infections and evaluated