Brigacent™

Brigatinib Tablet

Presentation
Brigacent™ 90: Each film coated tablet contains Brigatinib INN 90 mg.
Brigacent™ 180: Each film coated tablet contains Brigatinib INN 180 mg.

Description
Brigatinib is a potent and selective multi-targeted receptor tyrosine kinase inhibitor that blocks both anaplastic lymphoma kinase (ALK) and epidermal growth factor receptor (EGFR).

Indications and Uses
Brigatinib is a kinase inhibitor that is indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

Dosage and Administrations
90 mg orally once daily for the first 7 days followed by a dose increase to 180 mg orally once daily with or without food

Side-effects
The most common adverse reactions (≥25%) with Brigatinib were diarrhea, fatigue, nausea, rash, cough, myalgia, headache, hypertension, vomiting, and dyspnea.

Contraindications
None.

Warnings & Precautions
• Interstitial Lung Disease (ILD)/Pneumonitis: Monitor for new or worsening respiratory symptoms, particularly during the first week of treatment. Withhold Brigatinib for new or worsening respiratory symptoms and promptly evaluate for ILD/pneumonitis. Upon recovery, either reduce the dose or permanently discontinue Brigatinib.
• Hypertension: Monitor blood pressure after 2 weeks and then at least monthly during treatment. For severe hypertension, withhold Brigatinib, then dose reduce or permanently discontinue.
• Bradycardia: Monitor heart rate and blood pressure regularly during treatment. If symptomatic, withhold Brigatinib, then either reduce the dose or permanently discontinue.
• Visual Disturbance: Advise patients to report visual symptoms. Withhold Brigatinib and obtain ophthalmologic evaluation, then either reduce the dose or permanently discontinue Brigatinib.
• Creatine Phosphokinase (CPK) Elevation: Monitor CPK levels regularly during treatment. Based on the severity and with muscle pain or weakness, withhold Brigatinib, then resume or reduce dose.
• Pancreatic Enzymes Elevation: Monitor lipase and amylase levels regularly during treatment. Based on the severity, withhold Brigatinib, then resume or reduce dose.
• Hyperglycemia: Assess fasting serum glucose prior to starting Brigatinib and regularly during treatment. If not adequately controlled with optimal medical management, withhold Brigatinib, then consider dose reduction or permanently discontinue, based on severity.
• Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use a non-hormonal method of effective contraception

Use in special population

Pregnancy and Lactation
Pregnancy Category D. Brigatinib can cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies of Brigatinib in pregnant women.
It is not known whether Brigatinib 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 Brigatinib, 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.

Pediatric Use
The safety and effectiveness of Brigatinib in pediatric patients have not been established.

Geriatric Use
No overall differences in safety or effectiveness of Brigatinib were observed between these patients and younger patients.

Hepatic Impairment
No dose adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A) or moderate hepatic impairment (Child-Pugh B). Dose must be reduced for patients with severe hepatic impairment (Child-Pugh C).

Renal Impairment
No dose adjustment is recommended for patients with mild or moderate renal impairment. Dose must be reduced for patients with severe renal impairment.

Drug Interactions
• CYP3A4 Inhibitors: Avoid use of strong or moderate CYP3A4 inhibitors. If co-administration is warranted, reduce the dose of Brigatinib
• CYP3A4 Inducers: Avoid use of strong or moderate CYP3A4 inducers. If co-administration is warranted, increase the dose of Brigatinib

Storage
Do not store above 30 ^{0} C. Keep away from light and out of the reach of children.

Commercial Pack
Brigacent™ 90: Each box contains 1 blister strip of 7 tablets
Brigacent™ 180: Each box contains 1 blister strip of 7 tablets

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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