Dacocent™ 45

Dacomitinib Tablet

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Presentation

Dacocent™45: Each film coated tablet contains Dacomitinib Monohydrate INN equivalent to Dacomitinib 45 mg

Description

Dacomitinib is an irreversible inhibitor of the kinase activity of the human EGFR family (EGFR/HER1, HER2, and HER4)and certain EGFR activating mutations (exon 19 deletion or the exon 21 L858R substitution mutation). In vitro Dacomitinib also inhibited the activity of DDR1, EPHA6, LCK, DDR2, and MNK1 at clinically relevant concentrations. Dacomitinib demonstrated dose-dependent inhibition of EGFR and HER2 autophosphorylation and tumor growth in mice bearing subcutaneously implanted human tumor xenografts driven by HER family targets including mutated EGFR. Dacomitinib also exhibited antitumor activity in orally-dosed mice bearing intracranial human tumor xenografts driven by EGFR amplifications.

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Indications and Usage

Dacomitinib is a kinase inhibitor indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

Dosage and Administrations

The recommended dosage of Dacomitinib is 45 mg taken orally once daily, until disease progression or unacceptable toxicity occurs. Dacomitinib can be taken with or without food.

Take Dacomitinib the same time each day. If the patient vomits or misses a dose, do not take an additional dose or make up a missed dose but continue with the next scheduled dose.

Dosage Modifications for Adverse Reactions

Dose Level	Dose (Once Daily)
First dose reduction	30 mg
Second dose reduction	15 mg

Side Effects

Most common adverse reactions (incidence >20%) are diarrhea, rash,paronychia, stomatitis, decreased appetite, dry skin, decreased weight,alopecia, cough, and pruritus.

Warnings & Precautions

- Interstitial Lung Disease (ILD): Permanently discontinue DACOMITINIB if ILD is confirmed
- Diarrhea: Withhold and reduce the dose of DACOMITINIB based on the severity
- Dermatologic Adverse Reactions: Withhold and reduce the dose of DACOMITINIB based on the severity
- Embryo-Fetal Toxicity: DACOMITINIB can cause fetal harm. Advise females of reproductive potential to use effective contraception.

Contraindications

None

Use in specific populations

Pregnancy & Lactation: Dacomitinib can cause fetal harm when administered to a pregnant woman. There is no information regarding the presence of dacomitinib or its metabolites in human milk or their effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in breastfed infants from Dacomitinib,advise women not to breastfeed during treatment with DACOMITINIB and for at least 17 days after the last dose.

Pediatric Use: The safety and effectiveness of DACOMITINIB in pediatrics have not been established.

Geriatric Use: Exploratory analyses across this population suggest a higher incidence of Grade 3 and 4 adverse reactions (67% versus 56%,respectively), more frequent dose interruptions (53% versus 45%, respectively), and more frequent discontinuations (24%versus 10%, respectively) for adverse reactions in patients 65 years or older as compared to those younger than 65 years.

Females and Males of Reproductive Potential: Advise females of reproductive potential to use effective contraception during treatment with DACOMITINIB and for at least 17days after the final dose.

Drug Interaction

- Proton Pump Inhibitors (PPIs): Avoid use with DACOMITINIB; use locally-acting antacids or H2-receptor antagonist; administer DACOMITINIB at least 6 hours before or 10 hours after H2-receptor antagonist
- CYP2D6 Substrates: Avoid concomitant use with DACOMITINIB where minimal increases in concentration of the CYP2D6 substrate may lead to serious or life-threatening toxicities

Storage

Do not store above 30 ºC. Keep away from light and out of the reach of children.

Commercial Packaging

Dacocent™45: Each box contains 1 blister strip of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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