PULMONARY

Intestinal long disease (ID/Peumonitis)

PERMANENTLY DISCONTINUE Osimertinib.

Cardiac

QTc interval longer than 500 msec or on at least 2 separate ECGs.

PERMANENTLY DISCONTINUE Osimertinib.

Cardiovascular

Asymptomatic, absolute decrease in LVEF of 10% from baseline and below 50%.

PERMANENTLY DISCONTINUE Osimertinib.

Symptomatic congestive heart failure

If improvement to Grade 2 or better, resume at 40 mg daily. If no improvement within 3 weeks, PERMANENTLY DISCONTINUE Osimertinib.

Target Organ

Adverse Reactiona

Dose Modification

Pulmonary

Intestinal long disease (ID/Peumonitis)

PERMANENTLY DISCONTINUE Osimertinib.

Cardiac

QTc interval longer than 500 msec or on at least 2 separate ECGs.

PERMANENTLY DISCONTINUE Osimertinib.

Cardiovascular

Asymptomatic, absolute decrease in LVEF of 10% from baseline and below 50%.

PERMANENTLY DISCONTINUE Osimertinib.

Symptomatic congestive heart failure

If improvement to Grade 2 or better, resume at 40 mg daily. If no improvement within 3 weeks, PERMANENTLY DISCONTINUE Osimertinib.

Other

If improvement to Grade 0/2 within 3 weeks.

PERMANENTLY DISCONTINUE Osimertinib.

Drug Interaction

Avoid concomitant administration of Osimertinib with strong CYP3A inhibitors, which include macrolide antibiotics (e.g., Telithromycin, azithromycin) and diltiazem, verapamil, quinidine, and ketoconazole, as concomitant use of strong CYP3A inhibitors may increase Osimertinib plasma concentrations. If no alternative exists, monitor patients more closely for adverse reactions of Osimertinib.

Strong CYP3A inhibitors

Avoid concomitant administration of Osimertinib with strong CYP3A inhibitors, such as ketoconazole, itraconazole, and diltiazem, verapamil, quinidine, and ketoconazole, as concomitant use of strong CYP3A inhibitors may increase Osimertinib plasma concentrations. If no alternative exists, monitor patients more closely for adverse reactions of Osimertinib.

Strong CYP3A inducers

Avoid concomitant administration of Osimertinib with strong CYP3A inducers, such as phenytoin, rifampicin, carbamazepine, St. John's Wort or other strong CYP3A inducers, may decrease Osimertinib plasma concentrations. Effect on other drugs

Avoid concomitant administration of Osimertinib with drugs that are sensitive substrates of CYP3A, breast cancer resistance protein (BCRP), or P-gp with narrow therapeutic indices, including but not limited to Fentanyl, Cyclosporine, Quinidine, Ergot Alkaloids, Phenytoin, Carbamazepine, as Osimertinib may increase or decrease plasma concentrations of these drugs.

PHARMACOLOGICAL INFORMATION

Storage Conditions

Store in a cool and dry place, away from light. Keep out of the reach of children.

Presentation & Packaging

Tagrix 40 Tablet: Each commercial box contains 30 tablets in Alu-Alu blister pack.

Tagrix 80 Tablet: Each commercial box contains 30 tablets in Alu-Alu blister pack.

Manufactured by

BEACON Pharmaceuticals Limited

Mysuru, Karnataka.