Erlocent™

Erlotinib 100 & 150 mg

Presentation

Erlocent™100: Each tablet contains Erlotinib Hydrochloride INN equivalent to Erlotinib 100 mg.

Erlocent™150: Each tablet contains Erlotinib Hydrochloride INN equivalent to Erlotinib 150 mg.

Description

Erlotinib, a kinase inhibitor, is a quinazolinamine with the chemical name N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)4-quinazolinamine. Erlotinib reversibly inhibits the kinase activity of EGFR, preventing autophosphorylation of tyrosine residues associated with the receptor and thereby inhibiting further downstream signaling. Erlotinib binding affinity for EGFR exon 19 deletion or exon 21 (L858R) mutations is higher than its affinity for the wild type receptor. Erlotinib inhibition of other tyrosine kinase receptors has not been fully characterized.

Indications and Uses

Erlotinib is a kinase inhibitor indicated for:

Non-small cell lung cancer (NSCLC)

- The treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations receiving first-line, maintenance or second or greater line treatment after progression following at least one prior chemotherapy regimen

Pancreatic cancer

- First-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with Gemcitabine

Limitations of Use

- Erlotinib is not recommended for use in combination with platinum-based chemotherapy
- Safety and efficacy of Erlotinib have not been evaluated as first-line treatment in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution

Dosage and Administration

Non-small cell lung cancer (NSCLC): The recommended daily dose of Erlotinib for NSCLC is 150 mg.

Pancreatic cancer: The recommended daily dose of Erlotinib for pancreatic cancer is 100 mg taken once daily in combination with gemcitabine.

Erlotinib should be taken on an empty stomach, i.e., at least one hour before or two hours after the ingestion of food. Treatment should be continued until disease progression or unacceptable toxicity occurs.

Side-effects

The most common adverse reactions were rash, diarrhea, anorexia, fatigue, dyspnea, cough, nausea, and vomiting.

Contraindications

None

Precautions

- Interstitial Lung Disease (ILD): Occurs in 1.1% of patients. Erlotinib should be withheld for acute onset of new or progressive unexplained pulmonary symptoms, such as dyspnea, cough and fever. Erlotinib should be discontinued if ILD is diagnosed
- Renal Failure: Renal function and electrolytes should be monitored, particularly in patients at risk of dehydration. Erlotinib should be withheld for severe renal toxicity