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**Tarceva**

(Erlotinib) - Genentech

## THERAPEUTIC CLASS
Epidermal growth factor receptor tyrosine kinase inhibitor

## DEA CLASS
RX

## INDICATIONS
First-line 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; treatment of locally advanced or metastatic NSCLC after failure of at least 1 prior chemotherapy regimen; maintenance treatment of locally advanced or metastatic NSCLC that has not progressed after 4 cycles of platinum-based 1st-line chemotherapy. First-line treatment of locally advanced, unresectable, or metastatic pancreatic cancer in combination with gemcitabine.

## ADULT DOSAGE
*Adults:* Take on an empty stomach. NSCLC: Usual: 150mg qd. Pancreatic Cancer: Usual: 100mg qd in combination with gemcitabine. Continue until disease progression or unacceptable toxicity occurs. Refer to PI for dose modifications/discontinuation.

## HOW SUPPLIED
Tab: 25mg, 100mg, 150mg

## WARNINGS/PRECAUTIONS
Not recommended for use in combination with platinum-based chemotherapy. Serious interstitial lung disease (ILD) may occur; withhold for acute onset of new/progressive unexplained pulmonary symptoms. Renal failure; hepatotoxicity with or without hepatic impairment; hepatorenal syndrome; bullous, blistering, and exfoliative skin conditions; myocardial infarction (MI)/ischemia; cerebrovascular accidents (CVA); microangiopathic hemolytic anemia with thrombocytopenia; and fetal harm may occur. Decreased tear production, abnormal eyelash growth, keratoconjunctivitis sicca, or keratitis may occur and can lead to corneal perforation/ulceration. GI perforation may occur; increased risk in patients with prior history of peptic ulceration or diverticular disease.

## ADVERSE REACTIONS
Rash, diarrhea, anorexia, fatigue, dyspnea, cough, N/V, infection, stomatitis, pruritus, dry skin, conjunctivitis, keratoconjunctivitis sicca, back pain, chest pain.

## DRUG INTERACTIONS
Concomitant use with antiangiogenic agents, corticosteroids, NSAIDs, and/or taxane-based chemotherapy may increase risk of GI perforation. Increased levels with potent CYP3A4 inhibitors (eg, ketoconazole), and with inhibitors of both CYP3A4 and CYP1A2 (eg, ciprofloxacin). Decreased levels with CYP3A4 inducers (eg, rifampicin). Cigarette smoking and drugs affecting gastric pH (eg, omeprazole, ranitidine) may decrease levels. INR elevations and bleeding events reported with coumarin-derived anticoagulants (eg, warfarin); monitor PT/INR regularly.

## PREGNANCY
Category D, not for use in nursing.

## MECHANISM OF ACTION
EGFR tyrosine kinase inhibitor; reversibly inhibits the kinase activity of EGFR, preventing autophosphorylation of tyrosine residues associated with the receptor and thereby inhibiting further downstream signaling.

## PHARMACOKINETICS
**Absorption:** Bioavailability (60% without food, 100% with food); $T_{max}$=4 hrs. **Distribution:** $V_d$=232L; plasma protein binding (93%). **Metabolism:** CYP3A4 (major); 1A2, 1A1 (minor). **Elimination:** Feces (83%; 1% parent drug), urine (8%; 0.3% parent drug); $T_{1/2}$=36.2 hrs (median).

## ASSESSMENT
Assess for hepatic/renal impairment, dehydration, history of peptic ulceration or diverticular disease, pregnancy/nursing status, and possible drug interactions.

## MONITORING
Monitor for signs and symptoms of ILD, hepatotoxicity, GI perforation, MI/ischemia, renal failure/insufficiency, CVA, microangiopathic hemolytic anemia with thrombocytopenia, ocular disorders, bullous and exfoliative skin disorders, and other adverse reactions. Monitor LFTs, renal function, and serum electrolytes.

## PATIENT COUNSELING
Inform of risks/benefits of therapy. Instruct to notify physician if onset or worsening of skin rash or development of bullous lesions or desquamation; severe/persistent diarrhea, N/V, anorexia; unexplained SOB or cough; or eye irritation occurs. Instruct to stop smoking and advise to contact physician for any changes in smoking status. Advise on the presentation of skin, hair, and nail disorders. Instruct on initial

management of rash or diarrhea. Counsel on pregnancy planning and prevention; advise females of reproductive potential to use highly effective contraception during treatment and for at least 2 weeks after the last dose. Advise to contact physician if pregnant or if pregnancy is suspected and to d/c nursing during treatment.

## ADMINISTRATION/STORAGE

**Administration:** Oral route. Take on an empty stomach (at least 1 hr ac or 2 hrs pc). **Storage:** 25°C (77°F); excursions permitted to 15-30°C (59-86°F).