







GENERIC NAME: erlotinib

### **DRUG CLASS AND MECHANISM**

Erlotinib is a synthetic or man-made drug that is used for treating cancer. It is approved for treatment of non-small cell lung cancer (NSCLC).

There are more than 1.2 million cases worldwide of lung cancer each year, causing one death every 3 seconds. According to the National Cancer Institute, lung cancer is responsible for nearly 30% of cancer deaths in the US. NSCLC is the most common form of lung cancer and accounts for almost 80% of all the cases.

Many cells, including cancer cells, have receptors on their surfaces for epidermal growth factor (EGF), a protein that is normally produced by the body and that promotes the growth and multiplication of cells. When EGF attaches to epidermal growth factor receptors (EGFRs), it causes an enzyme called tyrosine kinase to become active within the cells. Tyrosine kinase triggers chemical processes that cause the cells, including cancer cells, to grow, multiply, and spread. Erlotinib attaches to EGFRs and thereby blocks the attachment of EGF and the activation of tyrosine kinase. This mechanism for stopping cancer cells from growing and multiplying is very different from the mechanisms of chemotherapy and hormonal therapy.

Erlotinib was approved by the FDA in November of 2004.

PRESCRIPTION: Yes

**PREPARATIONS:** Erlotinib is available as 25, 100, and 150 mg white, round tablets.

### **STORAGE**

Erlotinib should be stored at room temperature, 15-30°C (59-86°F). All drugs should be kept out of the reach of children.

# PRESCRIBED FOR

Erlotinib is used for patients with metastatic or locally advanced non-small cell lung cancer (NSCLC) who have failed at least one previous round of chemotherapy.

Patients who received erlotinib had an average survival of 6.7 months compared to 4.7 months in patients who received placebo. In addition, 31% of patients receiving erlotinib in the study were alive at one year compared to 22% of patients receiving placebo.

It is expected that erlotinib will be approved for the treatment of pancreatic cancer in 2005. Erlotinib also is being studied as a treatment for other cancers including ovarian and head and neck cancers.

## DOSING

The usual dose of erlotinib is 150 mg taken at least one hour before or two hours after eating to avoid an interaction with food that may reduce absorption of erlotinib.

## **DRUG INTERACTIONS**

CYP3A4 is an enzyme in the liver that breaks-down and helps to eliminate erlotinib from the body. Drugs that inhibit CYP3A4 can result in high levels of erlotinib in the body, and the high levels can result in toxicity from erlotinib. Such drugs include atazanavir (Reyataz), clarithromycin (Biaxin), indinavir (Crixivan), itraconazole (Sporanox), ketoconazole (Nizoral), nefazodone (Serzone), nelfinavir (Viracept), ritonavir (Norvir), saquinavir (Invirase; Fortovase), telithromycin (Ketek), and voriconazole (VFEND). In patients receiving these drugs, a lower dose of erlotinib may be needed to prevent toxicity.

Some drugs increase the activity of the enzyme CYP3A4 and the elimination of erlotinib may reduce the levels of erlotinib in the body and the drug ineffective. Drugs that do this include rifampicin (Rifadin), rifabutin (Mycobutin), rifapentine (Priftin), phenytoin (Dilantin), carbamazepine (Tegretol), phenobarbital and St. John's Wort. These drugs should be

avoided in patients taking erlotinib, if possible. If alternative drugs are not an option, higher doses of erlotinib may be required.

#### SIDE FEFFCTS

The most common side effects due to erlotinib are rash, diarrhea, loss of appetite, and fatigue. Any of these can occur in about half of all patients who receive the medicine, but these effects are usually mild. There have been rare reports of serious lung disease, including deaths, in patients receiving erlotinib for treatment of NSCLC or other tumors.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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