137mm

214mm

ERLONIB 100mg, 150mg Tablet

(E r l o t i n i b)

ایرلونب ۱۰۰ ملی گرام، ۱۵۰ ملی گرام ٹیبلٹ

(ایرلوٹینب)

COMPOSITION:

Erlonib Tablet 100mg

Each film coated tablet contains:

Erlotinib Hydrochloride (MS) eq. to Erlotinib.....100mg

Erlonib Tablet 150mg

Each film coated tablet contains:

Erlotinib Hydrochloride (MS) eq.to Erlotinib.....150mg

Product complies Innovator`s specs.

DESCRIPTION:

ERLONIB (erlotinib), a kinase inhibitor, is a quinazolinamine with the chemical name N-(3-ethynylphenyl)-6, 7-bis (2-methoxyethoxy)-4-quinazolinamine. ERLONIB contains erlotinib as the hydrochloride. Erlotinib hydrochloride has the molecular formula C22H23N3O4.HCl and a molecular weight of 429.90. The molecule has a pKa of 5.42 at 25oC. Erlotinib hydrochloride is very slightly soluble in water, slightly soluble in methanol and practically insoluble in acetonitrile, acetone, ethyl acetate and hexane.

Aqueous solubility of erlotinib hydrochloride is dependent on pH with increased solubility at a pH of less than 5 due to protonation of the secondary amine. Over the pH range of 1.4 to 9.6, maximal solubility of approximately 0.4 mg/mL occurs at a pH of approximately 2.

CLINICAL PHARMACOLOGY

Mechanism of Action

The mechanism of clinical antitumor action of erlotinib is not fully characterized. Erlotinib inhibits the intracellular phosphorylation of tyrosine kinase associated with the epidermal growth factor receptor (EGFR). Specificity of inhibition with regard to other tyrosine kinase receptors has not been fully characterized. EGFR is expressed on the cell surface of normal cells and cancer cells.

PHARMACOKINETICS

Absorption and Distribution:

Erlotinib is about 60% absorbed after oral administration and its bioavailability is substantially increased by food to almost 100%. Peak plasma levels occur 4 hours after dosing. The solubility of erlotinib is pH dependent. Erlotinib solubility decreases as pH increases. Co-administration of ERLOTINIB with omeprazole, a proton pump inhibitor, decreased the erlotinib exposure [AUC] and maximum concentration [Cmax] by 46% and 61% respectively. When ERLOTINIB was administered 2 hours following a 300 mg dose of ranitidine, an H2 receptor antagonist, the erlotinib AUC was reduced by 33% and Cmax by 54%. When ERLOTINIB was administered with ranitidine 150 mg twice daily (at least 10 h after the previous ranitidine evening dose and 2 h before the ranitidine morning dose), the erlotinib AUC and Cmax decreased by 15% and 17% respectively. Following absorption, erlotinib is approximately 93% protein bound to plasma albumin and alpha-1 acid glycoprotein (AAG). Erlotinib has an apparent volume of distribution of 232 liters.

Metabolism and Excretion:

A population pharmacokinetic analysis in 591 patients receiving the single-agent ERLOTINIB 2nd/3rd line regimen showed a median half-life of 36.2 hours. Time to reach steady state plasma concentration would therefore be 7 – 8 days. No significant relationships of clearance to covariates of patient age, body weight or gender were observed. Smokers had a 24% higher rate of erlotinib clearance.

An additional population pharmacokinetic analysis was conducted in 291 NSCLC patients administered single-agent erlotinib as maintenance treatment. This analysis demonstrated that covariates affecting erlotinib clearance in this patient population were similar to those seen in the prior single-agent pharmacokinetic analysis. No new covariate effects were identified.

A third population pharmacokinetic analysis was conducted that incorporated erlotinib data from 204 pancreatic cancer patients who received erlotinib plus gemcitabine. Similar results were observed to those seen in the prior single-agent pharmacokinetic analysis. No new covariate effects were identified. Coadministration of gemcitabine had no effect on erlotinib plasma clearance.

In vitro assays of cytochrome P450 metabolism showed that erlotinib is metabolized primarily by CYP3A4 and to a lesser extent by CYP1A2, and the extrahepatic isoform CYP1A1. Following a 100 mg oral dose, 91% of the dose was recovered: 83% in feces (1% of the dose as intact parent) and 8% in urine (0.3% of the dose as intact parent).

Cigarette smoking reduces erlotinib exposure. In the Phase 3 NSCLC trial, current smokers achieved erlotinib steady-state trough plasma concentrations which were approximately 2-fold less than the former smokers or patients who had never smoked. This effect was accompanied by a 24% increase in apparent erlotinib plasma clearance. In a separate study which evaluated the single-dose pharmacokinetics of erlotinib in healthy volunteers, current smokers cleared the drug faster than former smokers or volunteers who had never smoked. The AUC0-infinity in smokers was about 1/3 to 1/2 of that in never/former smokers. In another study which was conducted in NSCLC patients (N=35) who were current smokers, pharmacokinetic analyses at steady-state indicated a dose-proportional increase in erlotinib exposure when the ERLOTINIB dose was increased from 150 mg to 300 mg. However, the exact dose to be recommended for patients who currently smoke is unknown.

INDICATIONS AND USAGE

Non-Small Cell Lung Cancer (NSCLC)

ERLONIB (ERLOTINIB) monotherapy is indicated for the maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. ERLOTINIB monotherapy is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. Results from two, multicenter, placebo-controlled, randomized, Phase 3 trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of ERLOTINIB with platinum-based chemotherapy [carboplatin and paclitaxel or gemcitabine and cisplatin] and its use is not recommended in that setting

Pancreatic Cancer

ERLONIB (ERLOTINIB) in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer.

DOSAGE AND ADMINISTRATION

NSCLC (Non-Small Cell Lung Carcinoma)

The recommended daily dose of ERLONIB (ERLOTINIB) for NSCLC is 150 mg taken on an empty stomach at least one hour before or two hours after the ingestion of food. Treatment should continue until disease progression or unacceptable toxicity occurs. There is no evidence that treatment beyond progression is beneficial.

Pancreatic Cancer

The recommended daily dose of ERLONIB (ERLOTINIB) for pancreatic cancer is 100 mg taken on an empty stomach at least one hour before or two hours after the ingestion of food, in combination with gemcitabine .Treatment should continue until disease progression or unacceptable toxicity occurs.

Dose Modifications

In patients who develop an acute onset of new or progressive pulmonary symptoms, such as dyspnea, cough or fever, treatment with ERLOTINIB should be interrupted pending diagnostic evaluation. If Interstitial Lung Disease (ILD) is diagnosed, ERLOTINIB should be discontinued and appropriate treatment instituted as necessary. Discontinue ERLOTINIB for hepatic failure or gastrointestinal perforation. Interrupt or discontinue ERLOTINIB in patients with dehydration who are at risk for renal failure, in patients with severe bullous, blistering or exfoliative skin conditions, or in patients with acute /worsening ocular disorders.

Diarrhea can usually be managed with loperamide. Patients with severe diarrhea who are unresponsive to loperamide or who become dehydrated may require dose reduction or temporary interruption of therapy. Patients with severe skin reactions may also require dose reduction or temporary interruption of therapy. When dose reduction is necessary, the ERLOTINIB dose should be reduced in 50 mg decrements. In patients who are taking ERLOTINIB with a strong CYP3A4 inhibitor such as, but not limited to, atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, troleandomycin (TAO), voriconazole, or grapefruit or grapefruit juice, a dose reduction should be considered if severe adverse reactions occur. Similarly, in patients who are taking ERLOTINIB with an inhibitor of both CYP3A4 and CYP1A2 like ciprofloxacin, a dose reduction of ERLOTINIB should be considered if severe adverse reactions occur.

Pre-treatment with the CYP3A4 inducer rifampicin decreased erlotinib AUC by about 2/3 to 4/5. Use of alternative treatments lacking CYP3A4 inducing activity is strongly recommended. If an alternative treatment is unavailable, an increase in the dose of ERLOTINIB should be considered as tolerated at two week intervals while monitoring the patient's safety. The maximum dose of ERLOTINIB studied in combination with rifampicin is 450 mg. If the ERLOTINIB dose is adjusted upward, the dose will need to be reduced immediately to the indicated starting dose upon discontinuation of rifampicin or other inducers. Other CYP3A4 inducers include, but are not limited to rifabutin, rifapentine, phenytoin, carbamazepine, phenobarbital and St. John's Wort. These too should be avoided if possible.

Cigarette smoking has been shown to reduce erlotinib exposure. Patients should be advised to stop smoking. If a patient continues to smoke, a cautious increase in the dose of ERLOTINIB, not exceeding 300 mg may be considered, while monitoring the patient's safety. However, efficacy and long-term safety (> 14 days) of a dose higher than the recommended starting doses have not been established in patients who continue to smoke cigarettes. If the ERLOTINIB dose is adjusted upward, the dose should be reduced immediately to the indicated starting dose upon cessation of smoking.

Erlotinib is eliminated by hepatic metabolism and biliary excretion. Although erlotinib exposure was similar in patients with moderately impaired hepatic function (Child-Pugh B), patients with hepatic impairment (total bilirubin > ULN or Child-Pugh A, B and C) should be closely monitored during therapy with ERLOTINIB. Treatment with ERLOTINIB should be used with extra caution in patients with total bilirubin > 3 x ULN. ERLOTINIB dosing should be interrupted or discontinued if changes in liver function are severe such as doubling of total bilirubin and/or tripling of transaminases in the setting of pretreatment values outside normal range. In the setting of worsening liver function tests, before they become severe, dose interruption and/or dose reduction with frequent liver function test monitoring should be considered. ERLOTINIB dosing should be interrupted or discontinued if total bilirubin is >3 x ULN and/or transaminases are >5 x ULN in the setting of normal pretreatment values.

WARNINGS AND PRECAUTIONS

Pulmonary Toxicity

There have been reports of serious Interstitial Lung Disease (ILD)-like events, including fatalities, in patients receiving ERLOTINIB for treatment of NSCLC, pancreatic cancer or other advanced solid tumors. In the randomized single-agent NSCLC studies , the incidence of serious ILD-like events in the ERLOTINIB treated patients versus placebo treated patients was 0.7% versus 0% in the maintenance study and 0.8% for both groups in the 2nd and 3rd line study. In the pancreatic cancer study - in combination with gemcitabine –, the incidence of ILD-like events was 2.5% in the ERLOTINIB plus gemcitabine group vs. 0.4% in the placebo plus gemcitabine group.

The overall incidence of ILD-like events in approximately 32,000 ERLOTINIB-treated patients from all studies (including uncontrolled studies and studies with concurrent chemotherapy) was approximately 1.1%.

Reported diagnoses in patients suspected of having ILD-like events included pneumonitis, radiation pneumonitis, hypersensitivity pneumonitis, interstitial pneumonia, interstitial lung disease, obliterative bronchiolitis, pulmonary fibrosis, Acute Respiratory Distress Syndrome and lung infiltration. Symptoms started from 5 days to more than 9 months (median 39 days) after initiating ERLOTINIB therapy. In the lung cancer trials most of the cases were associated with Confounding or contributing factors such as concomitant/prior chemotherapy, prior radiotherapy, pre-existing parenchymal lung disease, metastatic lung disease, or pulmonary infections. In the event of an acute onset of new or progressive unexplained pulmonary symptoms such as dyspnea, cough, and fever, ERLOTINIB therapy should be

Interrupted pending diagnostic evaluation. If ILD is diagnosed, ERLOTINIB should be discontinued and appropriate treatment instituted as needed

Renal Failure

Cases of hepatorenal syndrome, acute renal failure (including fatalities), and renal insufficiency have been reported. Some were secondary to baseline hepatic impairment while others were associated with severe dehydration due to diarrhea, vomiting, and/or anorexia or concurrent chemotherapy use. In the event of dehydration, particularly in patients with contributing risk factors for renal failure (eg, pre-existing renal disease, medical conditions or medications that may lead to renal disease, or other predisposing conditions including advanced age), ERLOTINIB therapy should be interrupted and appropriate measures should be taken to intensively rehydrate the patient. Periodic monitoring of renal function and serum electrolytes is recommended in patients at risk of dehydration.

Hepatotoxicity

Cases of hepatic failure and hepatorenal syndrome (including fatalities) have been reported during use of ERLOTINIB, particularly in patients with baseline hepatic impairment. Therefore, periodic liver function testing (transaminases, bilirubin, and alkaline phosphatase) is recommended. In the setting of worsening liver function tests, dose interruption and/or dose reduction with frequent liver function test monitoring should be considered. ERLOTINIB dosing should be interrupted or discontinued if total bilirubin is >3 x ULN and/or transaminases are >5 x ULN in the setting of normal pretreatment values.

Patients with Hepatic Impairment

In a pharmacokinetic study in patients with moderate hepatic impairment (Child-Pugh B) associated with significant liver tumor burden, 10 out of 15 patients died on treatment or within 30 days of the last ERLOTINIB dose. One patient died from hepatorenal syndrome, 1 patient died from rapidly progressing liver failure and the remaining 8 patients died from progressive disease.

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Six out of the 10 patients who died had baseline total bilirubin > 3 x ULN suggesting severe hepatic impairment. Treatment with ERLOTINIB should be used with extra caution in patients with total bilirubin > 3 x ULN. Patients with hepatic impairment (total bilirubin > ULN or Child-Pugh A, B and C) should be closely monitored during therapy with ERLOTINIB. ERLOTINIB dosing should be interrupted or discontinued if changes in liver function are severe such as doubling of total bilirubin and/or tripling of transaminases in the setting of pretreatment values outside normal range.

Gastrointestinal Perforation

Gastrointestinal perforation (including fatalities) have been reported in patients receiving ERLOTINIB. Patients receiving concomitant anti-angiogenic agents, corticosteroids, NSAIDs, and/or taxane-based chemotherapy, or who have prior history of peptic ulceration or diverticular disease are at increased risk. . Permanently discontinue ERLOTINIB in patients who develop gastrointestinal perforation.

Bullous and Exfoliative Skin Disorders

Bullous, blistering and exfoliative skin conditions have been reported including cases suggestive of Stevens-Johnson syndrome/Toxic epidermal necrolysis, which in some cases were fatal. Interrupt or discontinue ERLOTINIB treatment if the patient develops severe bullous, blistering or exfoliating conditions.

Myocardial Infarction/Ischemia

In the pancreatic carcinoma trial, six patients (incidence of 2.3%) in the ERLOTINIB/gemcitabine group developed myocardial infarction/ischemia. One of these patients died due to myocardial infarction. In comparison, 3 patients in the placebo/gemcitabine group developed myocardial infarction (incidence 1.2%) and one died due to myocardial infarction.

Cerebrovascular Accident

In the pancreatic carcinoma trial, six patients in the ERLOTINIB/gemcitabine group developed cerebrovascular accidents (incidence: 2.3%). One of these was Hemorrhagic and was the only fatal event. In comparison, in the placebo/gemcitabine group there were no cerebrovascular accidents.

Microangiopathic Hemolytic Anemia with Thrombocytopenia

In the pancreatic carcinoma trial, two patients in the ERLOTINIB/gemcitabine group developed microangiopathic hemolytic anemia with thrombocytopenia (incidence: 0.8%). Both patients received ERLOTINIB and gemcitabine concurrently. In comparison, in the placebo/gemcitabine group there were no cases of microangiopathic hemolytic anemia with thrombocytopenia.

Ocular Disorders

Corneal perforation or ulceration have been reported during use of ERLOTINIB. Other ocular disorders including abnormal eyelash growth, keratoconjunctivitis sicca or keratitis have been observed with ERLOTINIB treatment and are known risk factors for corneal ulceration/perforation. Interrupt or discontinue ERLOTINIB therapy if patients present with acute/worsening ocular disorders such as eye pain.

Elevated International Normalized Ratio and Potential Bleeding

International Normalized Ratio (INR) elevations and infrequent reports of bleeding events, including gastrointestinal and non-gastrointestinal bleeding, have been reported in clinical studies, some associated with concomitant warfarin administration. Patients taking warfarin or other coumarin-derivative anticoagulants should be monitored regularly for changes in prothrombin time or INR.

Use in Pregnancy

ERLONIB (ERLOTINIB) can cause fetal harm when administered to a pregnant woman. Erlotinib administered to rabbits during organogenesis at doses that result in plasma drug concentrations of approximately 3 times those in humans at the recommended dose of 150 mg daily, was associated with embryo fetal lethality and abortion. When erlotinib was administered to female rats prior to mating and through the first week of pregnancy, at doses 0.3 or 0.7 times the clinical dose of 150 mg, on an mg/m2 basis, there was an increase in early resorptions that resulted in a decrease in the number of live fetuses.

There are no adequate and well-controlled studies in pregnant women using ERLOTINIB. Women of childbearing potential should be advised to avoid pregnancy while on ERLOTINIB. Adequate contraceptive methods should be used during therapy, and for at least 2 weeks after completing therapy. If ERLOTINIB is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reactions rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.Safety evaluation of ERLOTINIB is based on more than 1200 cancer patients who received ERLOTINIB as monotherapy, more than 300 patients who received ERLOTINIB 100 or 150 mg plus gemcitabine, and 1228 patients who received ERLOTINIB concurrently with other chemotherapies. There have been reports of serious events, including fatalities, in patients receiving ERLOTINIB for treatment of NSCLC, pancreatic cancer or other advanced solid tumors.

DRUG INTERACTIONS

ERLONIB (ERLOTINIB) is metabolized predominantly by CYP3A4, and inhibitors of CYP3A4 would be expected to increase exposure. Co-treatment with the potent CYP3A4 inhibitor ketoconazole increases erlotinib AUC by 2/3. When ERLOTINIB was co-administered with ciprofloxacin, an inhibitor of both CYP3A4 and CYP1A2, the erlotinib exposure [AUC] and maximum concentration [Cmax] increased by 39% and 17% respectively. Caution should be used when administering or taking ERLOTINIB with ketoconazole and other strong CYP3A4 inhibitors such as, but not limited to, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, troleandomycin (TAO), voriconazole and grapefruit or grapefruit juice.

Pre-treatment with the CYP3A4 inducer rifampicin for 7 days prior to ERLOTINIB decreased erlotinib AUC by about 2/3 to 4/5, which is equivalent to a dose of about 30 to 50 mg in NSCLC patients. In a separate study, treatment with rifampicin for 11 days, with co-administration of a single 450 mg dose of ERLOTINIB on day 8 resulted in a mean erlotinib exposure (AUC) that was 57.6% of that observed following a single 150 mg ERLOTINIB dose in the absence of rifampicin treatment. Use of alternative treatments lacking CYP3A4 inducing activity is strongly recommended. If an alternative treatment is unavailable, adjusting the starting dose should be considered. If the ERLOTINIB dose is adjusted upward, the dose will need to be reduced immediately to the indicated starting dose upon discontinuation of rifampicin or other inducers. Other CYP3A4 inducers include, but are not limited to, rifabutin, rifapentine, phenytoin, carbamazepine, phenobarbital and St. John's Wort.

Cigarette smoking has been shown to reduce erlotinib AUC. Patients should be advised to stop smoking; however, if they continue to smoke, a cautious increase in the dose of ERLOTINIB may be considered, while monitoring the patient's safety. If the ERLOTINIB dose is adjusted upward, the dose should be reduced immediately to the indicated starting dose upon cessation of smoking.

Pretreatment and co-administration of ERLOTINIB decreased the AUC of CYP3A4 substrate, midazolam, by 24%. The mechanism is not clear.

In a study, there were no significant effects of gemcitabine on the pharmacokinetics of erlotinib nor were there significant effects of erlotinib on the pharmacokinetics of gemcitabine.

Drugs that alter the pH of the upper GI tract may alter the solubility of erlotinib and reduce its bioavailability. Increasing the dose of ERLOTINIB when coadministered with such agents is not likely to compensate for the loss of exposure. Co-administration of ERLOTINIB with omeprazole, a proton pump inhibitor, decreased the erlotinib AUC by 46%. Since proton pump inhibitors affect pH of the upper GI tract for an extended period, separation of doses may not eliminate the interaction.

The concomitant use of proton pump inhibitors with ERLOTINIB should be avoided if possible. Co-administration of ERLOTINIB with 300 mg ranitidine, an H2 receptor antagonist, decreased erlotinib AUC by 33%. When ERLOTINIB was administered with ranitidine 150 mg twice daily (at least 10 h after the previous ranitidine evening dose and 2 h before the ranitidine morning dose), the erlotinib AUC decreased by 15%. If patients need to be treated with an H2-receptor antagonist such as ranitidine, it should be used in a staggered manner. ERLOTINIB must be taken once a day, 10 hours after the H2-receptor antagonist dosing and at least 2 hours before the next dose of H2-receptor antagonist. Although the effect of antacids on erlotinib pharmacokinetics has not been evaluated, the antacid dose and the ERLOTINIB dose should be separated by several hours, if an antacid is necessary.

USE IN SPECIFIC POPULATIONS

PREGNANCY

Pregnancy Category D

ERLONIB (ERLOTINIB) can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised not to become pregnant while being treated with ERLOTINIB. Erlotinib has been shown to cause maternal toxicity with associated embryo fetal lethality and abortion in rabbits when given at doses that result in plasma drug concentrations of approximately 3 times those in humans (AUCs at 150 mg daily dose). When given during the period of organogenesis to achieve plasma drug concentrations approximately equal to those in humans, based on AUC, there was no increased incidence of embryo fetal lethality or abortion in rabbits or rats.

However, female rats treated with 30 mg/m2/day or 60 mg/m2/day (0.3 or 0.7 times the clinical dose, on a mg/m2 basis) of erlotinib prior to mating through the first week of pregnancy had an increase in early resorptions that resulted in a decrease in the number of live fetuses.

No teratogenic effects were observed in rabbits or rats dosed with erlotinib during organogenesis at doses up to 600 mg/m2/day in the rabbit (3 times the plasma drug concentration seen in humans at 150 mg/day) and up to 60 mg/m2/day in the rat (0.7 times the clinical dose of 150 mg/day on a mg/m2 basis).

Nursing Mothers

It is not known whether erlotinib is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from ERLOTINIB, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of ERLONIB (ERLOTINIB) in pediatric patients have not been established.

Patients with Hepatic Impairment

Patients with hepatic impairment (total bilirubin > ULN or Child Pugh A, B and C) should be closely monitored during therapy with ERLONIB (ERLOTINIB). Treatment with ERLOTINIB should be used with extra caution in patients with total bilirubin > 3 x ULN.

In vitro and in vivo evidence suggest that erlotinib is cleared primarily by the liver. However, erlotinib exposure was similar in patients with moderately impaired hepatic function (Child-Pugh B) compared with patients with adequate hepatic function including patients with primary liver cancer or hepatic metastases.

Patients with Renal Impairment

Less than 9% of a single dose is excreted in the urine. No clinical studies have been conducted in patients with compromised renal function.

OVERDOSAGE

Single oral doses of ERLONIB (ERLOTINIB) up to 1,000 mg in healthy subjects and weekly doses up to 1,600 mg in cancer patients have been tolerated. Repeated twice-daily doses of 200 mg single-agent ERLOTINIB in healthy subjects were poorly tolerated after only a few days of dosing. Based on the data from these studies, an unacceptable incidence of severe adverse reactions, such as diarrhea, rash, and liver transaminase elevation, may occur above the recommended dose.

CONTRAINDICATIONS

ERLONIB (ERLOTINIB) is contraindicated in patients with hypersensitivity to erlotinib or to any of the excipients.

STORAGE & INSTRUCTIONS:

Store between 15-30°C. Protect from sunlight, heat and moisture. Keep out of the reach of children. **To be sold on the prescription of a registered oncologist or on demand from cancer hospitals, institutions and oncologists only.**

HOW SUPPLIED:

ERLONIB Tablet 100mg:

30 Film coated Tablets.

ERLONIB Tablet 150mg:

30 Film coated Tablets.

خوراک وطریقہ استعمال:

سرطان کے ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۳۰ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند اونکولوجسٹ یا کینسر ہسپتال کے نسخے پر فروخت کریں۔

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