Storage:
Store protected from light and moisture.
Keep out of the reach of children.

Presentation:
A strip of 10 Tablets.

References and further readings:
1) Elsevier Guide to Oncology drugs and Regimens 2005
2) Am J Pharmacogenomics 2005: 5(2) 133-136

HOPE LIFECARE
Health Optimises +ve Energy
D-190097
Marketed by:
HOPE Lifecare
Unit No 209, Anandraj Industrial Estate 2nd Floor,
Bhandup-Sonapur Lane,Bhandup West Mumbai 400078
Contact No.: 8080520460
Manufactured in India by:
Khandelwal Laboratories Pvt. Ltd.
B-1, Wagle Industrial Estate,Thane 400 604.
Regd. Office: 79/87, D. Lad Path, Mumbai - 400 033.

For the use of an Oncologist or a Hospital or a Laboratory only.

Gefinib Tablets IP 250mg

HOPEGEF

होपजेफ

Composition :
Each film coated tablet contains :
Gefitinib IP .....250 mg
Colour : Red Oxide of Iron, Yellow Oxide of Iron & Titanium Dioxide

Classification:
Antineoplastic signal transduction inhibitor

Warning:
Drug should be used only in cancer patients who have already taken it and whose physicians believe its benefitting them. New Patients should not receive it. Large study found that it did not extend Life

Pulmonary Toxicity:
In the event of acute onset or worsening of Pulmonary symptoms (dyspnea, cough, fever) Gefitinib therapy should be interrupted and a prompt investigation of these symptoms should occur
If interstitial lung disease is confirmed ,Gefitinib should be discontinued and the patient should be treated appropriately

Pregnancy: Category D
Gefitinib may cause fetal harm when administered to a pregnant woman.
There are no adequate and well-controlled studies in pregnant women using Gefitinib. If Gefitinib is used during pregnancy or if the patient becomes pregnant while receiving the drug. she should be appraised of the potential hazard to the fetus or potential risk for loss of the pregnancy.

Pharmacology:
Gefitinib may inhibit the activity of many tyrosine kinases associated with transmembrane cell surface receptors including those associated with the epidermal growth factor receptor (EGFR-TK). This effect ultimately blocks cell growth and reproduction. EGFR is expressed on cell surface

of many cells and cancer cells, including those in Colon, Lung, Head and Neck.

Pharmacokinetics :
Drug is metabolised in Liver. It peaks in 3-7 hours and achieves steady-state plasma concentrations in 10 days. Elimination half-life is 48 hours. It is excreted primarily in feces.

Indications and dosages:
Locally advanced or metastatic non-small cell lung cancer after failure of both platinum based and docetaxel chemotherapies.
Adult Dosage: 250mg P. O. Daily

Dose Modifications:
Drug is administered on continuous schedule over 28 days. It is given for 14 days on and 14 days off in patients with poorly tolerated diarrhea and adverse skin reactions.
If patient experiences acute onset or worsening of pulmonary symptoms (dyspnea, cough, fever), stop drug and initiate appropriate treatment. Discontinue drug if interstitial lung disease is confirmed.
For patients receiving potent CYP3A4 inducers, (such as rifampicin or phenytoin) consider increasing dosage to 500 mg daily in absence of severe adverse reactions.

Preparation and administration:
Do not crush or break film-coated tablet. Tablets can be dispersed only in half glass of non-carbonated drinking water. Drop tablet into water without crushing it and stir until it disperses. have patient drink immediately then rinse glass with water and drink again.
Drug may be given by naso-gastric tube if patient cannot swallow.

Contraindications and Precautions :
Contraindicated in hypersensitivity to drug or its components

Drug Interactions :
CYP3A4 inducers (such as rimfampin & phenytoin) increased Gefitinib metabiolism and decreased plasma concentration.

CYP3A4 inhibitors (such as ketoconazole itraconazole): decreased Gefitinib metabolism and increased plasma concentration.

Histamine receptor antagonists (such as ranitidine, cimetidine): decreased Gefitinib plasma concentration.

Warfarin increased INR, bleeding events.

Drug-diagnostic tests ALP, ALT, AST, serum bilirubin: possibly increases.

Adverse Reactions:
ENT: Conjuntivitis
GI: Diarrhea, nausea, Vomiting, anorexia.
Skin: Rash, Dry skin

Toxicity and overdosage:
- Anticipated overdose effects include increased frequency and severity of some adverse reactions mainly diarrhea and rash.
- Provide symptomatic treatment. In particular, manage severe diarrhea appropriately

Special Consideration:
- Monitor INB or prothrombin time regularly in patients receiving warfarin.
- Observe closely for interstitial lung disease, incidence is1% with one-third cases fatal.

Patient education:
- Please inform patient that drug may cause nausea, anorexia, vomiting or persistent diarrhea. Advise him/her to report these symptoms promptly if they persist.
- Advise patient to report eye irritation.
- Instruct patient to consume adequate fluids, especially if diarrhea occurs.
- Advise patient to promptly report new or worsening pulmonary symptoms such as dyspnea cough and fever.
- Advise women with child bearing potential to use effective contraception.
- Caution breast feeding patients not to breastfeed during therapy.