SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Gabisof (Gefitinib Tablets 250 mg)

2. Pharmaceutical Form
Pharmaceutical Dosage form of the product: Tablet
Strength: 250 mg
Route(s) of administration: Oral route of administration

3. Qualitative and Quantitative Composition
Label Claim:
Each film coated tablet contains
Gefitinib 250 mg
Colour: Red oxide of Iron, Yellow oxide of Iron and Titanium Dioxide

Sr. No.	Ingredients
1.	Gefitinib (with 2.5% overages) IH
2.	Lactose Monohydrate BP
3.	Microcrystalline Cellulose BP (Avicel pH 102)
4.	Polyvinyl Pyrrolidone K-30 BP
5.	Croscarmellose Sodium USNF
6.	Sodium Lauryl Sulphate BP
7.	Magnesium stearate BP
8.	Purified Water BP
Sr. No.	**Ingredients**
9.	Insta Coat Orange (IC-S-2269) IH
10.	Isopropyl Alcohol BP
11.	Methylene Chloride USNF

4. Clinical Particulars

4.1 Therapeutic indications

Locally advanced or metastatic non-small-cell lung cancer after failure of platinum based and docetaxel chemotherapies.

4.2 Posology and method of administration

Adult : 250mg P.O. Daily

Dosage modification

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 reaction.

If patient experience acute onset or worsening of pulmonary symptoms (such as dyspnea, cough, and fever), stop drug and initiate appropriate treatment. Discontinue drug if interstitial lung disease is confirmed.

For patient receiving acute CYP3A4 inducers) such as rifampin 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 tablets. Tablets can be dispersed only in half-glass of noncarbonated 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 nasogastric tube if patient cannot swallow.

4.3 Method of administration

Oral Route of Administration

4.4 Contraindications

Contraindicated in hypersensitivity to drug or its components.

Use cautiously in hepatic impairment, cardiac disease, severe renal impairment, and pregnancy or breastfeeding. Safety and efficacy in children have not been established.

4.5 Special warning and precautions for use

Warnings

Drug should be used only in cancer patients who have already taken it and whose physicians believe it is benefiting 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 patients should be treated appropriately.

4.6 Interaction with other medicinal products and other forms of Interactions

CYP3A4 inducers (such as rifampin, phenytoin): increased gefitinib metabolism and dicreased plasma concentration.
CYP3A4 inhibitors (such as ketoconazole, itracanazole): decreased gefitinib metabolism and increased plasma concentration.
Histamine$_2$ – receptor antagonists (such as ranitidine, cimetidine): decreased gefitinib plasma concentration.
Warfarin; increased INR, bleeding events.
Drug-dignostic tests. ALP, ALT, AST, serum bilirubin: possible increase.

4.7 Pregnancy

Pregnancy category D:
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 this Drug, she should be apprised of the potential hazard to the fetus or potential risk for loss of the pregnancy.
Pregnancy risk category D.

4.8 Effects on ability to drive and use machine

Not known.

4.9 Undesirable effects

Adverse Reactions
EENT: conjunctivitis
GI: Diarrhea, nausea, vomiting, anorexia
Skin: rash, acne, dry skin.

4.10 Overdose and special antidotes

Toxicity and overdose
Anticipated overdose effects include increased frequency and severity of some adverse reactions mainly diarrhea and rash.
Provide symptomatic treatment. Manage severe diarrhea appropriately.

Special consideration
Monitor INR or prothrombin time regularly in patients receiving warfarin. Observe closely for interstitial lung disease; incidences is 1%, with one-third of cases fatal.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Protein kinase inhibitors
ATC code: L01XE02

Pharmacology
Gefitinib may inhibit activity of many tyrosine kinases associated with transmembrane cell surface receptors, including those associated with epidermal growth factor receptor (EGFR)-TK. This effect ultimately blocks cell growth and reproduction. EGFR is expressed on cell surface of many normal cell and cancer cell, including those in colon, lung, head and neck.

5.2 Pharmacokinetic Properties

Drug is metabolized in liver. It peaks in 3 to 7 hours and achieves steady-state plasma concentrations in 10 days. Elimination half life is 48 hours. It is excreted primarily in feces.

6. Pharmaceutical Particulars

6.1 List of excipients

Lactose BP
Microcrystalline Cellulose BP
Polyvinyl Pyrrolidone K-30 BP
Croscarmellose sodium USNF
Sodium Lauryl Sulphate BP
Magnesium stearate BP
Purified Water BP
Instacoat Orange BP
Isopropyl Alcohol BP
Methylene Chloride USNF

6.2 Incompatibilities:

None

6.3 Shelf life

Shelf life of the medicinal product as package for sale.
24 Months

Shelf life after dilution or reconstitution according to directions.
Not Applicable

Shelf life first opening the container.
Not Applicable

6.4 Special precautions for storage
Store below 30˚C. Protect from Light.

6.5 Nature and contents of container
UNIT PACK: 10 tablets in a strip. Such one strip packed in a printed carton with pack insert

7. Marketing Authorization Holder and Manufacturing site address

Name of Marketing Authorization Holder:
Khandelwal Laboratories Pvt. Ltd.

Address of manufacturing site:
B-1, Wagle Industrial Estate,
Thane - 400 604, India
Telephone: 00 91 22 25821793 / 0794
Fax: 00 91 22 25823837

8. Marketing Authorization Numbers
09335/10128/NMR/2022

9. Date of first authorization / renewal of the authorization
Dec 23, 2023

10. Date of revision of the text
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