PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Gefitinib Teva

Coated tablets

250 mg

Composition

Each coated tablet contains:

Gefitinib 250 mg

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

The medicine is intended for adults over 18 years old.

1. What is the medicine intended for?

Therapeutic activity

Gefitinib Teva is intended for treatment of non-small cell lung cancer (NSCLC).

Gefitinib Teva is intended for treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC), with activating mutations of EGFR-TK.

Therapeutic class

Anti-cancer agents, EGFR (epidermal growth factor receptor) inhibitor.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, gefitinib, or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You are breastfeeding.

Special warnings regarding the use of the medicine:

During treatment with this medicine, liver function should be tested periodically.

Before treatment with Gefitinib Teva, inform the doctor if:

- You suffered in the past from other lung problems. Certain lung problems may be aggravated during treatment with Gefitinib Teva.
- You suffered in the past from liver problems.

Children and adolescents

Gefitinib Teva is not indicated for children and adolescents under the age of 18.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Phenytoin or carbamazepine (for epilepsy)
- Rifampicin (for tuberculosis)
- Itraconazole (for fungal infections)
- Barbiturates (medicines for treatment of sleep problems)
- Herbal medicines containing St. John's Wort (Hypericum perforatum, for depression and anxiety).
- Proton pump inhibitors, H_2 antagonists, antacids (for gastric ulcer, indigestion, heartburn and for reducing stomach acidity).

These medicines may affect the way Gefitinib Teva works.

- Warfarin (anti-coagulant medicine taken orally). If you are taking a medicine containing this active ingredient, the doctor may ask for more frequent blood tests.

If one of the above applies to you, or if you are unsure, you should check with your doctor or with a pharmacist before taking Gefitinib Teva.

Use of the medicine and food

The medicine can be taken with or without food.

Pregnancy and breastfeeding

Consult the doctor before taking Gefitinib Teva if you are pregnant, planning to become pregnant or are breastfeeding.

It is recommended to avoid becoming pregnant during treatment with Gefitinib Teva, since Gefitinib Teva may harm your baby.

Do not take Gefitinib Teva if you are breastfeeding, to protect your baby's health.

Driving and operating machinery

You may feel weak during treatment with Gefitinib Teva. In such a case, do not drive or operate any machinery.

Important information about some of the ingredients of the medicine

- Gefitinib Teva contains lactose. If you have been told by a doctor that you have an intolerance (sensitivity) to certain sugars, consult your doctor before taking this medicine.
- This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

One tablet once daily.

Do not exceed the recommended dose.

This medicine should be taken at set intervals, as determined by the treating doctor.

Follow the treatment as recommended by the doctor.

No information is available regarding halving the tablet.

Do not crush or chew the tablet. The medicine should be swallowed whole with water.

Do not take antacids (for reducing stomach acidity) two hours before or one hour after taking Gefitinib Teva.

The tablet may be added to half a glass of water (uncarbonated). Do not use other beverages. The tablet should be put in the water without crushing it. Mix until the tablet dissolves (about 20 minutes) and drink immediately. To ensure you took the entire dose, you should rinse the glass well with half a cup of water and drink it.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the emergency room of the hospital and take the package of the medicine with you.

If you forgot to take this medicine at the appointed time, take your dose as soon as you remember, so long as it is at least 12 hours before the time of the next dose. Never take two doses together.

If there are less than 12 hours left until the time of the next dose, do not take the forgotten dose.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Gefitinib Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Contact the doctor immediately if the following side effects occur, you may need urgent medical attention:

- Allergic reactions (common), especially if the signs include swelling of the face, lips, throat or tongue, difficulty swallowing, hives (allergic skin reaction) and breathing difficulties.
- Severe shortness of breath or a sudden aggravation of shortness of breath, which may be accompanied by cough or fever. Patients taking Gefitinib Teva may develop inflammation of the lungs called interstitial lung disease. This condition may occur in 1 out of 100 patients taking Gefitinib Teva and may be life-threatening.
- Dehydration (common) caused by severe or prolonged diarrhea, vomiting, nausea or loss of appetite.
- Eye problems (uncommon) such as pain, redness, teary eyes, sensitivity to light, altered vision or inward growing of eyelashes. This may indicate that you have an ulcer on the surface of the eye (the cornea).

Contact your doctor as soon as possible if you notice any of the following side effects:

Side effects occurring very frequently (effects that occur in more than 1 user out of 10):

- Diarrhea
- Vomiting
- Nausea
- Skin reactions, such as acne-like rash, sometimes accompanied by itching, dryness and/or cracks in the skin
- Loss of appetite
- Weakness
- Redness or ulcer in the mouth
- Elevation of the liver enzyme alanine aminotransferase in blood tests. If its value is too high, the doctor may tell you to stop taking Gefitinib Teva.

Common side effects (side effects that occur in 1-10 out of 100 users):

- Nail problems
- Dry mouth
- Hair loss
- Irritated, red and dry eyes
- Red and painful eyelids
- Nose bleeding, blood in the urine
- Fever
- Protein in the urine (observed in a urine test)
- Elevation in bilirubin and another liver enzyme - aspartate aminotransferase - observed in blood tests. If these values are too high, the doctor may tell you to stop taking Gefitinib Teva.
- Elevation in creatinine levels in blood tests (associated with kidney function).
- Inflammation of the bladder (burning sensation during urination, urinary frequency and urinary urgency).

Uncommon side effects (side effects that occur in 1-10 out of 1,000 users):

- Pancreatitis (pancreas inflammation), whose signs include very severe pain in the upper part of the abdomen, severe nausea and vomiting.
- Hepatitis (liver inflammation), whose signs may be general malaise with or without jaundice (yellow skin or eyes). This side effect is uncommon, although some patients died from it.
- Perforation in the digestive system.
- A skin reaction in the hands and feet, including tingling, numbness, pain, swelling or redness (known as palmar-plantar erythrodysaesthesia or the hand-foot syndrome).

Rare side effects (side effects that occur in 1-10 out of 10,000 users):

- Cutaneous vasculitis, a condition that may look like a bruise or areas with skin rash that does not become white when pressed.
- A bleeding inflammation of the bladder (burning sensation during urination, urinary frequency and urinary urgency with blood in the urine).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor!
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place under 25°C.**
- Do not discard an unneeded medicine in the trash. Please consult the pharmacist about how to dispose of it.

In case of a doubt, consult the pharmacist who dispensed the medicine to you.

Different medicines should not be stored in the same package.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, polyvinyl alcohol, magnesium stearate, macrogol, talc, sodium lauryl sulfate, iron oxide yellow, iron oxide red, titanium dioxide.

Each tablet contains 162.12 mg lactose (monohydrate).

Each tablet contains 0.20 mg sodium.

What does the medicine look like and what are the contents of the package:

A light brown to brown, round, convex tablet, debossed with "250" on one side of the tablet and plain on the other side.

The package contains 30 tablets.

Name and address of the manufacturer and marketing authorization holder:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv, 6944020.

The leaflet was revised in August 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 165.17.35616

teva