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

The medicine is dispensed with a doctor's prescription only

Erlotinib Teva 100 mg

Film-coated tablets

Erlotinib Teva 150 mg

Film-coated tablets

Composition

Each film-coated Erlotinib Teva 100 mg tablet contains:
Erlotinib 100 mg (as erlotinib hydrochloride)

Each film-coated Erlotinib Teva 150 mg tablet contains:
Erlotinib 150 mg (as erlotinib hydrochloride)

For information on inactive ingredients and allergens see section 2 under 'Important information about some of this medicine's ingredients' and section 6 - 'Additional information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

If you experience any side effects, refer to your doctor or pharmacist. This includes any possible side effects that are not listed in this leaflet (see section 4 - "Side Effects").

The medicine is not intended for use in children and adolescents below the age of 18.

Important information for your review
- Avoid pregnancy during the course of treatment with Erlotinib Teva, and do not breast-feed during the course of treatment with the medicine.
- It is recommended that you stop smoking while under treatment with Erlotinib Teva.
- Take the medicine on an empty stomach - at least one hour before or two hours after completing a meal. Do not take the medicine with grapefruits or with grapefruit juice.
- Erlotinib Teva contains a type of sugar called lactose.

1. What is the medicine intended for?

Therapeutic activity:
Erlotinib Teva contains the active ingredient erlotinib. Erlotinib Teva is a medicine used to treat cancer by preventing the activity of a growth factor protein called EGFR (epidermal growth factor receptor). This protein is known to be involved in the growth and spread of cancer cells.
Erlotinib Teva is intended for treatment of adults and can be prescribed for you in the following situations:
- Treatment of patients with advanced non-small cell lung cancer (NSCLC) if previous chemotherapy treatment was unsuccessful in stopping your disease.
- First line treatment in patients with advanced non-small cell lung cancer (NSCLC) if the cancer cells express mutations in EGFR.
- Treatment in patients with advanced non-small cell lung cancer (NSCLC) if the cancer cells express mutations in EGFR and your disease remains largely unchanged after initial chemotherapy treatment.
- Treatment in patients with advanced-stage or metastatic pancreatic cancer, in combination with standard medicinal treatment (gemcitabine).

Therapeutic group:
Antineoplastic, tyrosine kinase inhibitors

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (erlotinib) or to any of the medicine's ingredients (listed in section 6).
- You are breast-feeding.

Special warnings regarding the use of the medicine

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking other medicines that may increase or decrease the amount of the active ingredient (erlotinib) in your blood or influence its effect. Medicines such as:
- Antifungals (such as ketoconazole).
- Protease inhibitors - a group of antiviral medicines for treatment of AIDS/HIV and hepatitis C.
- Antibiotics (such as clarithromycin, erythromycin, ciprofloxacin).
- Medicines for epilepsy (such as phenytoin, carbamazepine).
- Sedatives and hypnotics (such as barbiturates).
- Medicines for tuberculosis (such as rifampicin).
- Proton pump inhibitors (such as omeprazole).
- H_2-receptor antagonist antihistamines (such as ranitidine).
- Medicines and herbal remedies for depression (such as St. John's wort).
- Proteasome inhibitors - a group of medicines to treat cancer.

In some cases, the following medicines may reduce the efficacy or increase the side effects of Erlotinib Teva, and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving Erlotinib Teva.
- Anticoagulants (medicines that help to prevent thrombosis or blood clotting, e.g., warfarin) since the medicine, Erlotinib Teva, may increase the tendency to bleed. Consult the doctor; he will need to regularly monitor you through blood tests.
- Medicines to lower your blood cholesterol level (statins) since the medicine, Erlotinib Teva, may increase the risk of muscle problems associated with statin treatment, which, on rare occasions, can lead to serious muscle cell breakdown (rhabdomyolysis), resulting in kidney damage. Consult with your doctor.
- If you are using contact lenses and/or have a history of eye problems such as severe dryness of the eyes, inflammations or ulcers in the front part of the eyes (cornea), consult the doctor.

Tell the doctor:
- If you have sudden difficulty in breathing associated with cough or fever since the doctor may give you other medicines and discontinue treatment with Erlotinib Teva.
- If you have diarrhea, since the doctor may give you an anti-diarrheal (for example loperamide).
- Immediately, if you have severe or persistent diarrhea, nausea, loss of appetite or vomiting since the doctor may discontinue the treatment with Erlotinib Teva and treat you in the hospital.
- If you have severe pain in the abdomen, severe blistering or peeling of skin. Your doctor may temporarily interrupt or permanently stop the treatment.
- If you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, refer to a doctor or nurse immediately, as you may need urgent treatment (see 'Side Effects' section below).
- If you are taking statins and experience unexplained muscle pain, muscle tenderness, muscle weakness or cramps. The doctor may stop the treatment.

For further information, see section 4 - 'Side Effects'.

Liver or kidney disease
It is not known whether Erlotinib Teva has a different effect in cases where your liver or kidneys are not functioning normally. The treatment with Erlotinib Teva is not recommended if you have a severe liver disease or severe kidney disease.

A metabolic disorder associated with glucuronidation, like Gilbert's syndrome
Your doctor must treat you with caution if you have a metabolic disorder associated with glucuronidation such as Gilbert's syndrome.

Children and adolescents
Erlotinib Teva has not been studied in patients under the age of 18 years. The treatment with this medicine is not intended for children and adolescents.

Use of Erlotinib Teva with food and drink
Do not take Erlotinib Teva with food (see section 3 - "How should you use the medicine?").
Take the medicine on an empty stomach - at least one hour before or two hours after completing a meal.
Do not take the medicine with grapefruits or with grapefruit juice.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, consult a doctor or pharmacist before using medicines.
Avoid pregnancy while being treated with Erlotinib Teva. If you are of child-bearing age and might become pregnant, you should use effective contraception during treatment with the medicine and for at least two weeks after taking the last tablet.
If you become pregnant during the course of treatment with Erlotinib Teva, immediately inform your doctor so he can decide if the treatment should be continued.
Do not breast-feed during the course of treatment with Erlotinib Teva and at least up to 2 weeks after taking the last tablet.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before using this medicine.

Driving and using machines
Erlotinib Teva has not been studied for its possible effects on the ability to drive or operate machinery; however, it is very unlikely that the treatment with Erlotinib Teva will affect these abilities.

Smoking
You are advised to stop smoking if you are being treated with Erlotinib Teva, as smoking could decrease the amount of the medicine in the blood.

Important information about some of this medicine's ingredients
Erlotinib Teva contains a sugar called lactose.
If you have been told by your doctor that you have an intolerance to some sugars, consult the doctor before starting treatment with this medicine.
Erlotinib Teva contains less than 23 mg sodium per tablet and is therefore considered sodium free.

3. How should you use the medicine?

Always use this medicine according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Usual dose
The dose and treatment regimen will be determined by the doctor only.
For treatment of lung cancer: The usual dose is generally one Erlotinib Teva 150 mg tablet a day.
For treatment of metastatic pancreatic cancer: The usual dose is generally one Erlotinib Teva 100 mg tablet a day. Erlotinib Teva will be given in combination with the standard medicinal treatment for this disease (gemcitabine).
Your doctor may adjust your dose in 50 mg increments. For the different dose regimens, Erlotinib Teva is available in strengths of 100 mg or 150 mg.

Do not exceed the recommended dose.

If you accidentally took a higher dose
Contact your doctor or pharmacist immediately.
You may have increased side effects and your doctor may stop your treatment.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forget to take the medicine
If you forgot to take one or more doses of the medicine, contact your doctor or pharmacist as soon as possible. If you forgot to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult the doctor.

If you stop taking the medicine
It is very important to keep taking Erlotinib Teva every day, as long as your doctor prescribes it for you.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Erlotinib Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to your doctor as soon as possible if you suffer from any of the following side effects. In some cases, your doctor might reduce your dose of Erlotinib Teva or stop the treatment:
- Diarrhea and vomiting (very common side effects that may affect more than 1 in 10 users). Severe or persistent diarrhea may lead to low blood potassium levels and impaired kidney function, particularly if you receive other chemotherapy treatments at the same time. If you experience severe or persistent diarrhea, refer to your doctor immediately; he may need to treat you in a hospital.
- Eye irritation due to conjunctivitis/keratoconjunctivitis (very common side effects that may affect more than 1 in 10 users) and keratitis (common side effect that may affect up to 1 in 10 users).
- A form of lung irritation called interstitial lung disease (this side effect is uncommon in European patients, but is common in Japanese patients. May affect up to 1 in 100 users in Europe and up to 1 in 10 users in Japan). This disease can be linked to the natural progression of your medical condition and in some cases, may have a fatal outcome. If you develop symptoms such as sudden difficulty in breathing associated with cough or fever, refer to your doctor immediately, as you could be suffering from this disease. Your doctor may decide to permanently stop your treatment with Erlotinib Teva.
- Gastrointestinal perforations have been observed (uncommon side effect that may affect up to 1 in 100 users). Refer to your doctor if you have severe pain in the abdomen. Also, tell your doctor if you had a peptic ulcer (a sore in the mucous membrane of the digestive system) or diverticular disease in the past, as these may increase the risk of perforations.
- In rare cases, liver failure was observed (rare side effect which may affect up to 1 in 1,000 users). If your blood tests indicate severe changes in liver function, the doctor may need to stop the treatment with Erlotinib Teva.

Additional side effects
Very common side effects (may affect more than 1 in 10 users):
- Skin rash which may occur or worsen in sun-exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreens are advisable
- Infections
- Loss of appetite, decreased weight
- Depression
- Headache, altered skin sensation or numbness in the extremities
- Difficulties in breathing, cough
- Nausea
- Mouth irritation
- Stomach pain, indigestion and flatulence (excessive amount of gas or air in the stomach or intestine)
- Abnormal blood tests for liver function
- Itching, dry skin and loss of hair
- Tiredness, fever, rigors

Common side effects (may affect up to 1 in 10 users):
- Nosebleed
- Bleeding from the stomach or the intestines
- Inflammatory reactions around the fingernails
- Infections in hair follicles
- Acne
- Cracked skin
- Reduced kidney function (when the medicine is given outside the approved indications in combination with chemotherapy)

Uncommon side effects (may affect up to 1 in 100 users):
- Eyelash changes
- Excess body and facial hair of a male distribution pattern
- Eyebrow changes
- Brittle or loose nails

Rare side effects (may affect up to 1 in 1,000 users):
- Flushed or painful palms or soles (Palmar-plantar erythrodysaesthesia syndrome)

Very rare side effects (may affect up to 1 in 10,000 users):
- Cases of perforation or ulceration of the cornea
- Severe blistering or peeling of the skin (suggestive of Stevens-Johnson syndrome)
- Inflammation of the colored part of the eye

If you experience any side effect, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: http://sideeffects.health.gov.il

5. How should the medicine be stored?

- 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 unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package and the blisters. The expiry date refers to the last day of that month.
- **Store the medicine below 25°C.**
- Do not discard the medicine in the household waste bin or in wastewater. Ask the pharmacist how to dispose of the medicine to protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:
Cellulose microcrystalline, lactose anhydrous, sodium starch glycolate type A, sodium laurylsulfate, sodium stearyl fumarate, silica hydrophobic colloidal
Tablet coating:
Hypromellose (E464), titanium dioxide (E171), macrogol/PEG 8000 (E1521)

Each Erlotinib Teva 100 mg tablet contains approximately 84 mg lactose.
Each Erlotinib Teva 150 mg tablet contains approximately 126 mg lactose.

What does the medicine look like and what are the contents of the package?
Erlotinib Teva 100 mg: white, round, biconvex film-coated tablets, engraved with A116 on one side.

Erlotinib Teva 150 mg: white, round, biconvex film-coated tablets, engraved with A127 on one side.

Each package contains 30 film-coated tablets.

Manufacturer and license holder and its address: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

This leaflet was revised in October 2021 according to MOH guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
Erlotinib Teva 100 mg film-coated tablets: 168.15.35874
Erlotinib Teva 150 mg film-coated tablets: 168.17.35876