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 in the medicine: see section 2 under 'Important information about some of this medicine's ingredients' and section 6 - 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.
- This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.
- This medicine is not intended for administration to children and adolescents below the age of 18 years.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Therapeutic activity:
Erlotinib Teva is intended for treatment of adults in the following situations:
- Advanced non-small cell lung cancer (NSCLC): First line treatment of patients with advanced non-small cell lung cancer (NSCLC) if the cancer cells express mutations in EGFR.
- Maintenance 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 of patients with advanced non-small cell lung cancer (NSCLC) if previous chemotherapy treatment was unsuccessful in stopping your disease.
- Treatment of patients with advanced-stage or metastatic pancreatic cancer, in combination with standard medicinal treatment (gemcitabine).

Therapeutic group: Antineoplastic, tyrosine kinase inhibitors

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are allergic (sensitive) to the active ingredient erlotinib or to any of the other ingredients that this medicine contains (see section 6 'Additional information' for complete list of the ingredients).

Special warnings regarding use of Erlotinib Teva

Interactions with other medicines
If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.
Before starting treatment with Erlotinib Teva, tell your doctor if:
- You are taking other medicines that may decrease or increase the level of erlotinib in the blood or influence the effect of the medicine (for example: antifungals such as ketoconazole, protease inhibitors, erythromycin, clarithromycin, phenytoin, carbamazepine, barbiturates, rifampicin, ciprofloxacin, omeprazole, ranitidine, St. John's wort or proteasome inhibitors). In some cases, these medicines may reduce the efficacy or increase the side effects of erlotinib, and your doctor will need to adjust your dosage. Your doctor might avoid treating you with these medicines while you are taking Erlotinib Teva.
- You are taking anticoagulants (medicines that prevent blood clotting or venous thrombosis, e.g., warfarin). Erlotinib Teva may cause a tendency to bleed. The doctor will need to perform blood tests for you regularly.
- You are taking statins (medicines to lower blood cholesterol). Erlotinib Teva may cause muscle pain, which, on rare occasions, may lead to muscle breakdown (rhabdomyolysis), which may result in kidney damage.
- 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.
- You have diarrhea, since the doctor may give you an anti-diarrheal (for example loperamide).
- Tell the doctor immediately if you have severe or persistent diarrhea, nausea, loss of appetite or vomiting. The doctor may discontinue the treatment with Erlotinib Teva and treat you in the hospital.
- You have liver problems. Erlotinib Teva may cause severe liver problems, and death in certain cases. The doctor can ask you to perform blood tests while taking Erlotinib Teva.
- You have severe abdominal pain, severe blistering or peeling of skin. Your doctor may temporarily interrupt or permanently stop the treatment.
- You experience rapid/acute onset or worsening of redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, contact a doctor or nurse immediately. You may need urgent treatment (see 'Side Effects' section below).
- You are taking statins and experience unexplained muscle pain, muscle tenderness to touch, 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 the 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.

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.

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.

Using this medicine and food
Do not take Erlotinib Teva with food (see section 3 - 'How to you use this medicine?').

Pregnancy and breastfeeding
Avoid pregnancy while being treated with Erlotinib Teva.
If you are a woman 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 can be continued.

Do not breastfeed 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 breastfeeding, 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.

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 TO USE THIS MEDICINE?

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

Take the medicine at least 1 hour before food or 2 hours after food.
For treatment of lung cancer: The usual dosage is generally one Erlotinib Teva 150 mg tablet a day.
For treatment of metastatic pancreatic cancer: The usual dosage 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 dosage in 50 mg increments. For the different dosage regimens, Erlotinib Teva is available in strengths of 100 mg or 150 mg.

Crushing/splitting/chewing
There is no information regarding crushing/splitting/chewing.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose
If you have taken too much Erlotinib Teva, call your doctor immediately. You may have increased side effects and your doctor may stop your treatment.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, go to a hospital emergency room immediately and bring the medicine package 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.

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

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

4. SIDE EFFECTS

As with any medicine, using Erlotinib Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Consult your doctor as soon as possible if you suffer from any of the following side effects. In some cases, your doctor might reduce your dosage 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 decreased 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, contact 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 the European population, but is common in the Japanese population. 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, contact 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). Contact your doctor if you have severe abdominal pain. 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 dysfunction was observed (rare side effect which may affect up to 1 in 1,000 users). The symptoms may include malaise, with or without jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and abdominal pain. Liver failure was observed in rare cases. This may be fatal. 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 tips of extremities
- Difficulties in breathing, cough
- Nausea
- Mouth irritation
- Abdominal pain, indigestion and flatulence
- Abnormal blood tests for liver function
- Itching, dry skin and hair loss
- Tiredness, fever, rigors

Common side effects (may affect up to 1 in 10 users):
- Nosebleeds
- 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 any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects due to Medicinal Treatment' found on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and all other medicines should be kept in a safe 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 a doctor!
- Do not take Erlotinib Teva after the expiry date (exp. date) which appears 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 dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help 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 laurilsulfate, 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 the medicine looks like and contents of the package:
Erlotinib Teva 100 mg: white, round, biconvex film-coated tablets, engraved with A116 on one side of the tablet.

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

Each package contains 30 film-coated tablets.

Name and address of the manufacturer and license holder: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv.

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

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