Patient Leaflet in Accordance With the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

ERLOTINIB TARO 25 mg
ERLOTINIB TARO 100 mg
ERLOTINIB TARO 150 mg
Film-coated tablets

Name and quantity of active ingredient

Each film-coated tablet contains:

erlotinib 25 mg (as erlotinib hydrochloride)

erlotinib 100 mg (as erlotinib hydrochloride)

erlotinib 150 mg (as erlotinib hydrochloride)

Inactive ingredients and allergens in this 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 to treat your illness. Do not pass it on to others; it may harm them, even if it seems to you that their illness is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Erlotinib Taro is intended for treatment of adults in the following situations:

NSCLC (non-small cell lung cancer):
- First line treatment in patients with locally advanced or metastatic NSCLC if the cancer cells express mutations in EGFR.
- Maintenance treatment in patients with locally advanced or metastatic NSCLC if the cancer cells express mutations in EGFR and the disease remains largely unchanged after initial chemotherapy treatment.
- Treatment of patients with locally advanced or metastatic NSCLC if at least one previous chemotherapy treatment was unsuccessful in stopping the disease.

Pancreatic cancer:
- First line treatment in patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine.

Therapeutic group: antineoplastics, tyrosine kinase inhibitors

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Before using this medicine, tell your doctor:

- If you have sudden difficulty in breathing associated with cough or fever, because the doctor may give you other medicines and stop treatment with Erlotinib Taro.
- If you have diarrhea, because 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, because your doctor may stop the treatment with Erlotinib Taro and treat you in the hospital.
- If you have liver problems. Erlotinib Taro may cause serious liver problems and some cases may be fatal. Your doctor can ask you to perform blood tests while you are taking Erlotinib Taro**.**
- If you have severe abdominal pain, severe blistering or peeling of skin. Your doctor may temporarily interrupt or permanently stop the treatment.
- If you experience rapid/acute onset or worsening of redness and pain in the eyes, watery eyes, blurred vision and/or sensitivity to light. Consult a doctor or nurse immediately, as you may need urgent treatment (see the section 'Side effects' below).
- If you are taking statins and experience unexplained muscle pain, muscle tenderness, muscle weakness or cramps. Your doctor may stop the treatment.
- 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 your doctor.

For further information, see section 4 – 'Side effects'.

Liver or kidney disease

It is not known whether Erlotinib Taro has a different effect in cases where the liver or kidneys are not functioning normally. The treatment with Erlotinib Taro is not recommended if you have 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 (glucuronidation disorder), such as Gilbert's syndrome.

Smoking

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

Children and adolescents

Erlotinib Taro has not been studied in patients under the age of 18 years. Treatment with this medicine is not intended for children and adolescents.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Particularly if you are taking other medicines that may increase or decrease the amount of the active ingredient (erlotinib) in your blood or influence its efficacy. 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).
- H2-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, these medicines can reduce the efficacy or increase the side effects of Erlotinib Taro and your doctor may need to adjust your dosage. Your doctor might avoid treating you with these medicines while you are taking Erlotinib Taro.
- Anticoagulants (medicines that prevent blood clotting or thrombosis, e.g., warfarin), as Erlotinib Taro may increase the tendency to bleed. Your doctor will need to regularly monitor you with blood tests.
- Medicines to lower blood cholesterol level (statins), as Erlotinib Taro may cause muscle pain, which, on rare occasions, may cause muscle breakdown (rhabdomyolysis), which may result in kidney damage.

Using this medicine with food and drink

Do not take Erlotinib Taro with food (see section 3 - 'How to use this medicine?').
Take the medicine on an empty stomach - at least one hour before or two hours after the end of a meal.
Do not take the medicine with grapefruit or grapefruit juice.

Pregnancy and breastfeeding

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.

Pregnancy

Avoid pregnancy while being treated with Erlotinib Taro. 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 Taro, immediately inform your doctor, who will decide if the treatment should be continued.

Breastfeeding

Do not breastfeed during the course of treatment with Erlotinib Taro and for at least two weeks after taking the last tablet.

Driving and using machines
Erlotinib Taro 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 Taro will affect these abilities.

Important information about some of this medicine's ingredients
Erlotinib Taro contains lactose. If you have been told by your doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.
Erlotinib Taro contains less than 1 mmol (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.

Usual dosage
Only your doctor will determine your dose and how you should take this medicine.
For treatment of lung cancer: The usual dosage is generally one Erlotinib Taro 150 mg tablet a day.
For treatment of metastatic pancreatic cancer: The usual dosage is generally one Erlotinib Taro 100 mg tablet a day. Erlotinib Taro will be given in combination with the standard therapy for this disease (gemcitabine).
Your doctor may adjust your dosage in 50 mg increments. For the different dosage regimens, Erlotinib Taro is available in strengths of 25 mg, 100 mg or 150 mg.
You may split the 100 mg tablet. There is no information regarding crushing and chewing the tablets.

Do not exceed the recommended dose.

If you have accidentally taken a higher dose
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, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you forget to take one or more doses of the medicine, contact your doctor or pharmacist as soon as possible. If you forget 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 Taro every day, as long as your doctor prescribes it for you. Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and 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 Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact your doctor as soon as possible if you suffer from any of the following side effects. In some cases, your doctor might reduce your Erlotinib Taro dosage 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 additional chemotherapy treatments at the same time. If you experience severe or persistent diarrhea, contact your doctor immediately; your doctor may need to treat you in a hospital.
- Eye irritation due to keratoconjunctivitis (a very common side effect that may affect more than 1 in 10 users) and keratitis and conjunctivitis (common side effects 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 may 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 Taro.
- Gastrointestinal perforations have been observed (uncommon side effect that may affect up to 1 in 100 users). Contact 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 (a rare side effect which may affect up to 1 in 1,000 users). Symptoms may include a general feeling of being unwell, with or without jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and abdominal pain. In rare cases, liver failure was observed. This may be fatal. If your blood tests indicate severe changes in liver function, your doctor may need to stop your treatment with Erlotinib Taro.

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
- Difficulty in breathing, cough
- Nausea
- Mouth irritation
- Stomach pain, indigestion and flatulence
- 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):
- 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 erythrodysesthesia 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 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?
- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions
- Store below 25°C.
- Do not throw away any medicine 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:
Tablet core:

cellulose microcrystalline, lactose monohydrate, sodium starch glycolate, cellulose, microcrystalline and calcium hydrogen phosphate, anhydrous, magnesium stearate, sodium lauryl sulfate, silica colloidal anhydrous.

Tablet coating:

hypromellose, hydroxypropylcellulose, titanium dioxide, macrogol.

What the medicine looks like and contents of the pack:
Erlotinib Taro 25 mg:
White, round, bi-convex, about 6 mm in diameter, film-coated tablet. The tablet is impressed with 'E9OB' on one side and '25' on the other.

Erlotinib Taro 100 mg:
White, round, bi-convex, about 10 mm in diameter, film-coated tablet with a score line on both sides. The tablet is impressed on one side with 'E9OB' above the score line and '100' below the score line.

Erlotinib Taro 150 mg:
White, round, bi-convex, about 10.4 mm in diameter, film-coated tablet. The tablet is impressed with 'E9OB' on one side and '150' on the other.

Each package contains 30 film-coated tablets packed in blisters.

Registration holder's name and address: Taro International Ltd, 14 Hakitor St., Haifa Bay 2624761, Israel

Manufacturer's name and address:

Synthon Chile Ltda, El Castano 145, Lampa, Santiago, Chile

Revised in July 2024.

Registration numbers of the medicines in the Ministry of Health National Drug Registry:
Erlotinib Taro 25 mg: 168-93-35955-00
Erlotinib Taro 100 mg: 168-92-35954-00
Erlotinib Taro 150 mg: 168-91-35932-00