



PACKAGE LEAFLET

TARSINIB 150 mg Film Coated Tablets

Taken by mouth.

Cytotoxic

Active substance: Each film-coated tablet contains 163.92 mg erlotinib hydrochloride equivalent to 150 mg erlotinib.

Excipient(s): Lactose monohydrate (pharmatose 200 M) (from cow's milk), microcrystalline cellulose (avicel pH 102), sodium starch glycolate (primojel), sodium lauryl sulfate (SLS), colloidal silicon dioxide (aerosil 200), magnesium stearate, *Opadry White OY 58900*; HPMC 2910/hypromellose, titanium dioxide, macrogol/PEG.

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you take this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or a **lower** dose other than recommended to you.*

What is in this leaflet:

- 1. What TARSINIB is and what it is taken for***
- 2. What you need to know before you take TARSINIB***
- 3. How to take TARSINIB***
- 4. Possible side effects***
- 5. How to store TARSINIB***

1. WHAT TARSINIB IS AND WHAT IT IS TAKEN FOR

- Each film-coated tablet contains 163.92 mg erlotinib hydrochloride equivalent to 150 mg erlotinib. It is in the form of biconvex, white, round film-coated tablets. It is available as 30 film-coated tablets in blisters of 10 tablets.
- It is a member of the drug group called antineoplastic drugs, which prevent the division and development of tumor cells.
- TARSINIB, containing erlotinib, is a medicine used to treat cancer by preventing the activity of a protein called epidermal growth factor receptor (EGFR). This protein is known to be involved in the growth and spread of cancer cells. TARSINIB is indicated for adults and can be prescribed to you for the first or second line treatment if you have a specific EGFR mutation (a type of genetic defect) in your cancer cell and you have metastatic non-squamous non-small cell lung cancer.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TARSINIB

DO NOT TAKE TARSINIB

- If you are allergic to erlotinib or to any of the other ingredients of TARSINIB.

Take special care with TARSINIB



If;

- You are taking other medicines that may increase or decrease the amount of erlotinib in your blood or influence its effect (for example antifungals such as ketoconazole; protease inhibitors used in viral infections like hepatitis; antibiotics such as erythromycin, clarithromycin, ciprofloxacin; epilepsy medicines such as phenytoin, carbamazepine; sedatives such as barbiturates; tuberculosis medicines such as rifampicin; peptic ulcer or reflux medicines such as omeprazole, ranitidine, or herbal medicines such as St. John's Wort, Hypericum perforatum used for depression, or proteasome inhibitors). In some cases, these medicines may reduce the efficacy or increase the side effects of TARSINIB and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving TARSINIB.
- You are taking anticoagulants (a medicine which helps to prevent thrombosis or blood clotting e.g. warfarin) TARSINIB may increase your tendency to bleed, and your doctor will need to regularly monitor you with some blood tests.
- You are taking statins (medicines to lower your blood cholesterol), TARSINIB may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage.
- You use contact lenses and/or have a history of eye problems such as severe dry eyes, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye, tell your doctor.

See also the warning in section “*Other medicines and TARSINIB*” below.

If:

- You have sudden difficulty in breathing associated with cough or fever, talk to your doctor, because your doctor may need to treat you with other medicines and interrupt your TARSINIB treatment;
- You have diarrhea, talk to your doctor, because your doctor may need to treat you with anti-diarrheal (for example loperamide).
- You have severe and persistent diarrhea, nausea, loss of appetite, or vomiting, talk to your doctor immediately, because your doctor may need to interrupt your TARSINIB treatment and may need to treat you in the hospital.
- You have severe pain in the abdomen, severe blistering or peeling of skin, your doctor may need to interrupt or stop your treatment.
- You develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, please tell your doctor or nurse immediately as you may need urgent treatment (see *Possible side effects* below).
- You are also taking a statin and experience unexplained muscle pain, tenderness, weakness or cramps, your doctor may need to interrupt or stop your treatment.

See also section “*Possible side effects*”.

Patients under the age of 18 years:

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

Liver or kidney disease:

It is not known whether TARSINIB has a different effect if your liver or kidneys are not



functioning normally. The treatment with TARSINIB is not recommended if you have a severe liver disease or severe kidney disease.

Glucuronidation disorder similar to Gilbert's syndrome:

Your doctor must treat you with caution if you have a glucuronidation disorder (a metabolic event that allows the breakdown of medicines and nutrients) like Gilbert's syndrome (a type of mild liver disorder).

Smoking

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

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

TARSINIB with food and drink

Do not take TARSINIB with food (see *How to take TARSINIB*). Also, caution should be exercised when using with grapefruit and grapefruit juice, in such cases your doctor may need to reduce your TARSINIB dose.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

Avoid pregnancy while being treated with TARSINIB. If you have the potential to become pregnant, you should use an adequate contraception method during treatment, and for at least 2 weeks after taking the last tablet.

During your treatment, if you realize that you're pregnant, consult your doctor or pharmacist immediately.

Your doctor will decide if the treatment should be continued.

Breastfeeding

Consult your doctor or pharmacist before using this medicine.

Do not breast-feed your baby during your treatment with TARSINIB and for at least 2 weeks after taking your last dose.

Driving and using machines

No studies have been conducted on the effects on the ability to drive and use machines. But it is very unlikely that TARSINIB treatment will affect your ability to drive and use machines.

Important information regarding some excipients in TARSINIB

TARSINIB contains 106.28 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TARSINIB.

Other medicines and TARSINIB

If you are using a medicine that will lower or increase the amount of erlotinib in your blood (for example, fungicides such as ketoconazole, protease inhibitors used in viral infections



such as hepatitis; antibiotics such as erythromycin, clarithromycin, ciprofloxacin; epilepsy drugs such as phenytoin, carbamazepine; sedatives such as barbiturates; tuberculosis medicines such as rifampicin; proton pump inhibitors such as omeprazole, peptic ulcer medications such as ranitidine and reflux medications, or herbal remedies such as St. John's Wort), in some cases these medicines may decrease the effectiveness of TARSINIB or increase its side effects and your doctor may readjust your treatment. While you are undergoing TARSINIB treatment, your doctor may avoid treatment with these drugs.

If you are using an anticoagulant (a drug that helps prevent blood clotting or thrombosis (blood clotting in the vein), such as warfarin), TARSINIB may increase your tendency to bleed and your doctor may need to monitor you with some regular blood tests.

If you are using statins (a medicine to lower your blood cholesterol), TARSINIB may increase the risk of muscle problems, which can rarely cause severe statin-related muscle deterioration (rhabdomyolysis) and result in kidney damage.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE TARSINIB

- **Instructions for proper use and dose/frequency of administration:**

Always take TARSINIB exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablet should be taken at least 1 hour before or 2 hours after the ingestion of food.

The usual erlotinib dose is 1 tablet of 150 mg each day if you have non-small cell lung cancer.

Your doctor may adjust your dose in 50 mg steps. For the different dose regimens, TARSINIB is available in strengths of 25 mg, 100 mg or 150 mg.

- **Method and route of administration:**

Taken by mouth with a glass of water.

- **Different age groups:**

Use in children: Use of erlotinib in patients under 18 years of age have not been studied. This medicine is not recommended for use in children and adolescents.

Use in the elderly: Use of erlotinib in elderly patients have not been studied. It has no special use.

- **Special conditions for use:**

Kidney failure:

It is not known whether TARSINIB has a different effect if your kidneys are not functioning normally. The treatment with TARSINIB is not recommended if you have a severe kidney disease.

Liver failure:

Your doctor will adjust the dose of your medicine depending on your disease and apply it to



you, if your liver are not functioning normally. The treatment with TARSINIB is not recommended if you have a severe liver disease.

If you have an impression that the effect of TARSINIB is too strong or too weak, talk to your doctor or pharmacist.

If you take more TARSINIB than you should:

Talk to a doctor or pharmacist if you have taken more TARSINIB than you should.

You may have increased side effects and your doctor may interrupt your treatment.

If you forget to take TARSINIB:

If you miss one or more doses of TARSINIB, contact your doctor or pharmacist as soon as possible.

Do not take a double dose to make up for a missed dose.

Possible side effects when treatment with TARSINIB is terminated:

It is important to keep using TARSINIB every day, as long as your doctor gives it for you. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, TARSINIB may cause side effects in people sensitive to the ingredients.

Side effects are classified in the following frequencies:

Very common	: may occur in at least 1 in 10 patients.
Common	: may occur in less than 1 in 10 but more than 1 in 100 patients.
Uncommon	: may occur in less than 1 in 100 but more than 1 in 1,000 patients.
Rare	: may occur in less than 1 in 1,000 but more than 1 in 10,000 patients.
Very rare	: may occur in less than 1 in 10,000 patients.
Not known	: cannot be estimated from the available data.

See your doctor as soon as possible if you suffer from any of the below side effects. In some cases, the doctor may need to reduce the TARSINIB dose or interrupt treatment:

- Diarrhea and vomiting (very common). Persistent and severe diarrhea may lead to low blood potassium and impairment of your kidney function, particularly if you receive other chemotherapy treatments at the same time. If you experience more severe or persistent diarrhea, **contact your doctor immediately** as your doctor may need to treat you in the hospital.
- Eye irritation due to inflammation of the conjunctival layer of the eye (very common) and eye irritation due to inflammation of the clear body of the eye (cornea) (common), uveitis (a type of eye inflammation).
- A rare type of lung irritation called interstitial lung disease (uncommon). This disease can also be linked to the natural progression of your medical condition and can have a fatal outcome in some cases. If you develop symptoms such as sudden difficulty in breathing associated with cough or fever contact your doctor immediately. Your doctor may decide to permanently stop your treatment with TARSINIB.
- Gastrointestinal perforations (tear in the stomach or intestines) have been observed (uncommon). Tell your doctor if you have severe pain in your abdomen. Also, tell your



doctor if you had peptic ulcers (a sore that develops in the stomach or intestines, sometimes in the esophagus) or diverticular disease (herniations in the wall of the digestive tract) in the past, as this may increase this risk.

- In rare cases, liver failure was observed. If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.

Very common side effects:

- Rash, which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreen (mineral-containing) may be advisable
- Infection
- 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 the liver function
- Itching, dry skin and loss of hair (alopecia)
- Tiredness, fever, convulsions

Common side effects:

- Bleeding from the nose
- Bleeding from the stomach or the intestines
- Inflammatory reactions around the fingernail
- Infection of hair follicles
- Acne
- Cracked skin
- Reduced kidney function (when given outside the approved indications in combination with chemotherapy)

Uncommon side effects:

- Eyelash changes
- Excess body and facial hair of a male distribution pattern
- Eyebrow changes
- Brittle and loose nails

Rare side effects:

- Flushed or painful palms or soles (erythrodysesthesia, also known as hand-foot syndrome)

Very rare side effects:

- Corneal ulcer (wound area that develops on the corneal surface, which is the transparent part of the eye) or perforation (hole)
- Severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome, a serious skin disease)
- Inflammation of the colored part of the eye



If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TARSINIB

Keep TARSINIB out of reach and sight of children in its original package.

Store at room temperature below 30°C and protect from moisture.

Use in line with the expiry date.

Do not take TARSINIB after the expiry date, which is stated on the package.

Do not use TARSINIB if you notice any defects in the product and/or its package.

Cytotoxic drugs, their secondary packages and equipment/materials used in the preparation/administration of these drugs are considered **HAZARDOUS WASTE** and should be disposed according local regulations and guidelines.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:

DEVA Holding A.Ş.
Küçükçekmece – ISTANBUL / TÜRKİYE

Manufacturing site:

DEVA Holding A.Ş.
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