Applicant : Eurolab (Pty) Ltd
Proprietary name : Tarpib 25 mg & 100 mg & 150 mg
Dosage form and strength : Film-coated tablets 25 mg & 100 mg & 150 mg
Date of submission : 12 February 2025
Approval date : 23 May 2025

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

TARPIB 25 mg (film-coated tablets)

TARPIB 100 mg (film-coated tablets)

TARPIB 150 mg (film-coated tablets)

Erlotinib hydrochloride equivalent to erlotinib

Contains sugar: Lactose monohydrate

Read all of this leaflet carefully before you start taking TARPIB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TARPIB has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What TARPIB is and what it is used for
2. What you need to know before you take TARPIB
3. How to take TARPIB

4. Possible side effects

5. How to store TARPIB

6. Contents of the pack and other information

1. What TARPIB is and what it is used for

TARPIB is used to treat cancer in adults 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.

TARPIB can be prescribed to you if you have non-small cell lung cancer at an advanced stage. TARPIB can be prescribed as initial therapy if your cancer cells have specific EGFR mutations. It can also be prescribed if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

TARPIB can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas which is spreading to other parts of your body (metastatic stage).

2. What you need to know before you take TARPIB

Do not take TARPIB:

- if you are hypersensitive (allergic) to erlotinib or any of the other ingredients of TARPIB (listed in section 6).

Warnings and precautions

Take special care with TARPIB:

- You are advised to stop smoking if you are treated with TARPIB as smoking could decrease the amount of TARPIB in your blood. If you have lung problems, such as interstitial lung disease (ILD), which includes different lung conditions which present with symptoms such as difficulty in breathing, cough and fever. You should tell your doctor if you have sudden difficulty in breathing associated with cough or fever because your doctor may need to treat you with other medicines and interrupt your TARPIB treatment.
- You should tell your doctor if you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal medicines. If you have severe or persistent diarrhoea, nausea, loss of appetite or vomiting your doctor may need to interrupt your TARPIB treatment and may need to treat you in the hospital.
- It is not known whether TARPIB has a different effect if your liver or kidneys are not functioning normally. The treatment with TARPIB is not recommended if you have severe liver disease or severe kidney disease.
- Tell your doctor if you have liver problems such as Gilbert's Syndrome, wherein the liver does not breakdown enzymes properly, causing yellowing of the skin or eyes (jaundice).
- If you have a history of stomach sores (ulcers) or other conditions in your stomach or intestines. If you have severe pain in the abdomen, your doctor may need to interrupt or stop your treatment with TARPIB.
- If you have a history of skin conditions, or if you experience severe blistering or peeling, your doctor may stop your treatment with TARPIB.

- If you use contact lenses or have a history of eye problems such as severe dry eyes, swelling of the front part of the eye (cornea) or ulcers involving the front part of the eye. If you experience sudden or worsening eye problems (e.g. eye pain), your doctor may need to interrupt or stop your treatment with TARPIB.
- If you are taking any other medication (see Other medicines and TARPIB).
- If you are pregnant or breastfeeding your baby.

Children and adolescents

The safety of TARPIB has not been established in patients younger than 18 years. Treatment with TARPIB is not recommended for children and adolescents.

Other medicines and TARPIB

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

Antibiotics (e.g. ciprofloxacin, erythromycin or clarithromycin, rifampicin): medicine used to treat bacterial infections including tuberculosis.

Antidepressants (e.g. fluvoxamine): medicine used to treat depression.

- Anaesthetics (e.g. midazolam): medicine used to cause drowsiness and lower anxiety before a surgical procedure.

- Anti-cancer medicines (e.g. paclitaxel, capecitabine, bortezomib): medicine used to treat specific cancers.
- Anti-fungal medicines (e.g. ketoconazole, itraconazole, voriconazole): medicine used to treat fungal infections.
- Anti-epileptics (e.g. phenytoin, carbamazepine): medicine used to treat fits or seizures.
- Central nervous system depressants (e.g. barbiturates): medicines used to cause sleepiness.
- St. Johns Wort (hypericum perforatum): herbal medicine used to treat depression.
- Anticoagulants (e.g. warfarin): medicine used to treat and prevent blood clots from forming.
- Statins (e.g. simvastatin, rosuvastatin, atorvastatin): medicines to lower your blood cholesterol.
- Immunosuppressants (e.g. ciclosporin): medicines used to treat inflammatory conditions or to prevent the body from rejecting an organ transplant.
- Anti-dysrhythmia medicines (e.g. verapamil): medicine used to treat problems with your heart rhythm.
- Medicines altering pH (e.g. omeprazole, ranitidine): medicines used to treat heartburn or wounds in your stomach or intestines (ulcers).

TARPIB with food

TARPIB be taken should be taken at least one hour before or two hours after the ingestion of food.

Pregnancy, breastfeeding and fertility

For men taking TARPIB

Men taking TARPIB should use highly effective contraception, while taking TARPIB and for an additional 4 months after taking the last dose.

For women taking TARPIB

Female patients and female sexual partners of male patients taking TARPIB should use highly effective contraception, while taking TARPIB and for an additional 7 months after taking the last dose.

You should not take TARPIB if you are pregnant or breastfeeding your baby.

If you become pregnant while you are being treated with TARPIB, immediately inform your healthcare provider who will decide if the treatment should be continued.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TARPIB.

Driving and using machines

TARPIB has not been studied for its possible effects on the ability to drive and use machines but it is very unlikely that your treatment will affect this ability.

It is not always possible to predict to what extent TARPIB may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TARPIB affects them.

3. How to take TARPIB

Do not share medicines prescribed for you with any other person.

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

The usual dose of TARPIB in adults is:

Non-small cell lung cancer: The usual dose is one 150 mg TARPIB tablet each day.

Pancreatic cancer: The usual dose is one tablet of TARPIB 100 mg each day. TARPIB is given in combination with gemcitabine treatment.

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

Your doctor will tell you how long your treatment with TARPIB will last.

TARPIB should be taken at least one hour before or two hours after the ingestion of food.

Swallow your tablet with a glass of plain water.

If you have the impression that the effect of TARPIB is too strong or too weak, tell your doctor or pharmacist.

If you take more TARPIB than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take TARPIB

If you have missed a dose of TARPIB, take the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for forgotten individual doses. If you have forgotten to take several doses, contact your doctor without delay.

4. Possible side effects

TARPIB can have side effects.

Not all side effects reported for TARPIB are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TARPIB, please consult your healthcare provider for advice.

If any of the following happens, stop taking TARPIB and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious reaction to TARPIB. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Sudden difficulty in breathing associated with cough or fever. This could be signs of a lung irritation called interstitial lung disease. This disease can have a fatal outcome in some cases. Your doctor may decide to permanently stop your treatment with TARPIB,
- bleeding from the stomach or the intestines. This condition can have a fatal outcome in some cases,
- liver failure, which may show signs such as yellowing of your skin or eyeballs (jaundice), pain or swelling in the upper right part of your stomach area, nausea, vomiting or a general sense of feeling unwell. This condition can have a fatal outcome in some cases,

- signs of pneumonia, an infection that inflames the air sacs in one or both lungs. The air sacs may fill with fluid causing cough with phlegm or pus, fever, chills and difficulty
- breathing,
- signs of sepsis, which is a life-threatening complication of an infection. Signs include patches of discoloured skin, passing less urine than normal, changes in mental ability, difficulty breathing, abnormal heart rate, chills,
- signs of cellulitis, which is a potentially serious bacterial skin infection. The affected skin appears swollen and red and is typically painful and warm to the touch,
- signs of kidney failure (renal insufficiency), which may show signs such as passing less urine than normal, retaining more fluid in your body, causing swelling in your legs, ankles or feet or shortness of breath.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Severe or persistent diarrhoea, nausea, vomiting, decreased weight or loss of appetite,
- acute or worsening redness, itchiness or pain in the eye, increased eye watering, blurred vision, sensitivity to light, swelling of the eye,
- feeling abnormally sad or down (depression),
- headache,
- weakness, numbness or pain, usually in your hands and feet (neuropathy),

- bleeding from the nose (epistaxis), cough,
- sores in the mouth (stomatitis),
- severe pain in the abdomen, heartburn (dyspepsia), passing gas (flatulence),
- abnormal blood tests for the liver function.
- rashes, itchy or dry skins, loss of hair (alopecia),
- inflammatory reactions around the fingernail (paronychia),
- infection of hair follicles, acne, cracked skin (skin fissures),
- tiredness, fever, sudden feeling of cold with shivers (rigors).

Less frequent side effects:

- Eyelash changes, eyebrow changes,
- cuts or wounds in the eye (corneal perforation or ulceration),
- excess body and facial hair of a male distribution pattern (hirsutism),
- brittle and loose nails,
- flushed or painful palms or soles (Palmar plantar erythrodysaesthesia syndrome),
- patches of skin appear darker than the surrounding skin (hyperpigmentation).
- Hepatitis

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website, or to Eurolab (Pty) Ltd. by email: drug-safety@eurolab.co.za.

By reporting side effects, you can help provide more information on the safety of TARPIB.

5. How to store TARPIB

Store all medicines out of reach of children. Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TARPIB contains

Each film-coated tablet of TARPIB 25 mg contains erlotinib hydrochloride equivalent to 25 mg erlotinib.

Contains sugar: Lactose monohydrate 23,98 mg

Each film-coated tablet of TARPIB 100 mg contains erlotinib hydrochloride equivalent to 100 mg erlotinib.

Contains sugar: Lactose monohydrate 95,93 mg

Each film-coated tablet of TARPIB 150 mg contains erlotinib hydrochloride equivalent to 150 mg erlotinib.

Contains sugar: Lactose monohydrate 143,90 mg

The other ingredients are lactose monohydrate, macrogol 3350 (E1521), magnesium stearate (E470b), methacrylic acid - ethyl acrylate copolymer (1:1) Type A, microcrystalline cellulose (E460), polyvinyl alcohol (E1203), sodium hydrogen carbonate, sodium starch glycolate Type A, talc (E553b), titanium dioxide (E171).

What TARPIB looks like and contents of the pack

TARPIB 25 mg tablets: White to yellowish, round biconvex, film-coated tablet, engraved with "25" on one side.

TARPIB 100 mg tablets: White to yellowish, round biconvex, film-coated tablet, engraved with "100" on one side.

TARPIB 150 mg tablets: White to yellowish, round biconvex, film-coated tablet, engraved with "150" on one side.

10 film-coated tablets are packed in silver Aluminium-OPA/Alu/PVC blister strips and 3 blister strips are packed into an outer cardboard carton.

Holder of Certificate of Registration

Eurolab (Pty) Ltd

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3 Stirrup Lane, Van Reenens Avenue,

Woodmead,

2144

This leaflet was last revised in

May 2025

Registration number

TARPIB 25 mg: 52/26/0773

TARPIB 100 mg: 52/26/0774

Applicant	: Eurolab (Pty) Ltd
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TARPIB 150 mg: 52/26/0775