Applicant/PHCR: DR REDDY'S LABORATORIES (PTY) LTD
Product proprietary name: EGROTIB 25 / 100 / 150
Dosage form: Tablets
Strengths: Each tablet contains erlotinib hydrochloride equivalent to 25 mg, 100 mg or 150 mg erlotinib respectively

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EGROTIB 25, 25 mg, tablets

EGROTIB 100, 100 mg, tablets

EGROTIB 150, 150 mg, tablets

Erlotinib

Contains sugar (lactose monohydrate)

EGROTIB 25

Each 25 mg film-coated tablet contains 16,667 mg lactose monohydrate.

EGROTIB 100

Each 100 mg film-coated tablet contains 66,667 mg lactose monohydrate.

EGROTIB 150

Each 150 mg film-coated tablet contains 100,000 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking EGROTIB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- EGROTIB 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.

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What is in this leaflet

1. What EGROTIB is and what it is used for

EGROTIB is a medicine used to treat cancer by preventing the activity of a protein called epidermal growth factor receptor. This protein is known to be involved in the growth and spread of cancer cells.

EGROTIB is indicated for adults.

EGROTIB can be prescribed to you if you have non-small cell lung cancer with EGFR activating mutation at an advanced stage. It can be prescribed either if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

EGROTIB can be prescribed to you if you have adenocarcinoma of your lung.
It can be prescribed as initial therapy if your cancer cells have specific EGFR mutations.

EGROTIB can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas at a metastatic stage (stage where the cancer has spread from the place where it started to another part of the body).

2. What you need to know before you take EGROTIB

Do not take EGROTIB

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

Warnings and precautions

Take special care with EGROTIB:

- 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 like ketoconazole, protease inhibitors, erythromycin, clarithromycin, phenytoin, carbamazepine, barbiturates, rifampicin, ciprofloxacin, omeprazole, ranitidine, St. John's Wort or proteasome inhibitors), talk to your doctor. In some cases these medicines may reduce the efficacy or increase the side effects of EGROTIB and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving EGROTIB.
- if you are taking anticoagulants (a medicine which helps to prevent thrombosis or blood clotting e.g. warfarin), EGROTIB may increase your tendency to bleed. Talk to your doctor, he will need to regularly monitor you with some blood tests.
- if you are taking statins (medicines to lower your blood cholesterol), EGROTIB may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage, talk to your doctor.
- if 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 below "Other medicines and EGROTIB".

You should tell your doctor:

- if you have <u>sudden</u> difficulty in breathing associated with cough or fever because your doctor may need to treat you with other medicines and interrupt your EGROTIB treatment.

- if you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal medicines (for example loperamide).
- immediately, if you have severe or persistent diarrhoea, nausea, loss of appetite or vomiting because your doctor may need to interrupt your EGROTIB treatment and may need to treat you in the hospital.
- if you have severe pain in the abdomen, severe blistering or peeling of skin. Your doctor may need to interrupt or stop your treatment.
- if 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).
- if 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 4 "Possible side effects".

Liver or kidney disease

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

Glucuronidation disorder like Gilbert's syndrome

Your doctor will treat you with caution if you have a disorder like Gilbert's syndrome, which can affect your liver and enzymes in your body, causing jaundice (yellowing of the skin and whites of the eyes).

Smoking

You are advised to stop smoking if you are treated with EGROTIB as smoking considerably decreases the amount of EGROTIB available in your blood.

Children and adolescents

EGROTIB safety has not been established in patients under the age of 18 years. Therefore, treatment with EGROTIB is not recommended for children and adolescents.

Other medicines and EGROTIB

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines or might take any other medicines.

Taking EGROTIB with food and drink

Do not take EGROTIB with food. See also section 3 'How to take EGROTIB'.

Pregnancy and breastfeeding

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 health care provider for advice before receiving this medicine.

Avoid pregnancy while being treated with EGROTIB. If you can become pregnant, use adequate contraception during treatment, and for at least 2 weeks after taking the last tablet. If you become pregnant while on treatment with EGROTIB, immediately inform your doctor. Women who are pregnant should not receive EGROTIB.

Do not breastfeed if you are being treated with EGROTIB, and for at least 2 weeks after taking the last tablet.

Driving and using machines

EGROTIB is very unlikely to affect your ability to drive and use machines.

EGROTIB contains a sugar called lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking EGROTIB.

3. How to take EGROTIB

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

Always take EGROTIB exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Non-small cell lung cancer and Bronchial adenocarcinoma: The usual dose is one 150 mg EGROTIB tablet each day.

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

Your doctor will tell you how long your treatment with EGROTIB will last. Do not stop treatment early.

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

Do not take EGROTIB with a meal. Take your EGROTIB tablet at least 1 hour before you eat or at least 2 hours after you have eaten. Swallow your tablet with a glass of plain water.

Your doctor may adjust your dose in 50 mg steps. For different dosage regimens, EGROTIB is available in strengths of 25 mg, 100 and 150 mg.

If you take more EGROTIB than you should

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

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

If you forget to take EGROTIB

Contact your doctor or pharmacist as soon as possible. Do not take a double dose to make up for forgotten individual doses.

If you stop taking EGROTIB

It is important to keep taking EGROTIB every day, as long as your doctor prescribes it for you. If you have any further questions on the use of EGROTIB, ask your doctor or pharmacist.

4. Possible side effects

EGROTIB can have side effects.

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

If any of the following happens, stop taking EGROTIB 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
- severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome)
- difficulty in breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to EGROTIB. 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:

- Diarrhoea and vomiting. Persistent and severe diarrhoea may lead to low blood potassium and impairment of your kidney function, particularly if you receive other chemotherapy

treatments at the same time.

- Eye irritation due to conjunctivitis/keratoconjunctivitis and keratitis.
- If you develop symptoms such as sudden difficulty in breathing associated with cough or fever (serious form of lung irritation called interstitial lung disease).
- If you have severe pain in your abdomen (gastrointestinal perforations) and if you had peptic ulcers or diverticular disease in the past, as this may increase this risk.
- Liver failure. If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.

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:

- rash
- rash which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sunscreen (e.g. mineral-containing) may be advisable
- diarrhoea
- itching, dry skin, loss of hair, inflammatory reactions around the fingernail
- acne, infection of hair follicles
- cracked skin (skin fissures)
- keratitis (inflammation of the cornea)
- loss of appetite, decreased weight
- nausea, vomiting, mouth irritation
- stomach pain, indigestion, flatulence
- tiredness, fever, rigors (a chill, usually with shivering, as at the onset of high fever)
- cough
- infection

- headache, altered skin sensation or numbness in the extremities
- depression
- abnormal blood tests for the liver function
- bleeding from the stomach or the intestines
- bleeding from the nose can occur.

Less frequent side effects:

- excess body and facial hair of a male distribution pattern, eyelash and eyebrow changes, brittle and loose nails, hyperpigmentation (patches of skin become darker in colour)
- uveitis, which is inflammation of the uvea of the eye
- ulceration or perforation of the cornea

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. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

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

5. How to store EGROTIB

Store all medicines out of reach of children.

- Store at or below 30 ºC
- Do not remove the blisters from the carton until required for use
- Do not use EGROTIB after the expiry date which is stated on the label and carton
- 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 EGROTIB contains

- The active substance is erlotinib.

  EGROTIB 25

  Each film-coated tablet contains 25 mg erlotinib (as erlotinib hydrochloride).

  EGROTIB 100

  Each film-coated tablet contains 100 mg erlotinib (as erlotinib hydrochloride).

  EGROTIB 150

  Each film-coated tablet contains 150 mg erlotinib (as erlotinib hydrochloride).

- The other ingredients are:

  Tablet core: Lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate, sodium starch glycolate Type A

  Tablet coat: Hydroxypropyl cellulose (E463), hypromellose (E464), macrogol, titanium dioxide (E171)

What EGROTIB looks like and contents of the pack

EGROTIB 25

White to off white film coated round tablets with 'E' de-bossed on one side and plain on other side.

EGROTIB 100

White to off white film coated round tablets with 'E' de-bossed on one side and '100' on other side.

EGROTIB 150

White to off white film coated round tablets with 'E' de-bossed on one side and '150' on other side.

Blister packs

EGROTIB 25 mg: Aluminium foil/PVC blisters containing 30 tablets per pack.

EGROTIB 100 mg: Aluminium foil/PVC blisters containing 30 tablets per pack.

EGROTIB 150 mg: Aluminium foil/PVC blisters containing 30 tablets per pack.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road,

Morningside,

Sandton,

2057

This leaflet was last revised in

Date of registration: 20 June 2023

Registration numbers

EGROTIB 25: 56/26/0128

EGROTIB 100: 56/26/0129

EGROTIB 150: 56/26/0130

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of

Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

1