Applicant : Eurolab (Pty) Ltd
Proprietary name : Gefirix
Dosage form and strength : Film-coated tablets 250 mg
Approval date : 26 October 2021

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

GEFIRIX 250 mg Film-coated tablets

Gefitinib

[Contains sugar (lactose)]

Read all of this leaflet carefully before you start taking GEFIRIX

- 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.
- **GEFIRIX** 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 **GEFIRIX** is and what it is used for
2. What you need to know before you take **GEFIRIX**
3. How to take **GEFIRIX**
4. Possible side effects
5. How to store **GEFIRIX**
6. Contents of the pack and other information

1 What GEFIRIX is and what it is used for

What GEFIRIX is

GEFIRIX contains the active substance ‘gefitinib’, that blocks a protein called ‘epidermal growth factor receptor’ (EGFR). This protein is involved in the growth and spread of cancer cells.

What GEFIRIX is used for

GEFIRIX is used to treat adults with non-small cell lung cancer. This cancer is a disease in which malignant (cancer) cells form in the tissues of the lung.

2 What you need to know before you take GEFIRIX

Do not take GEFIRIX

- if you are allergic (hypersensitive) to the active ingredient, gefitinib, or to any of the other ingredients in **GEFIRIX** (listed in section 6 of this leaflet).
- if you are breast feeding.
- if you are pregnant.

Warnings and Precautions

Special care should be taken with **GEFIRIX**

- Some lung problems may get worse during treatment with **GEFIRIX** . If you have ever had any other lung problems or experience worsening of respiratory symptoms such as shortness of breath, cough and fever.
- if you have a history of liver disease or complications.

Children and adolescents

GEFIRIX is not recommended for use in children and adolescents under 18 years.

Other medicines and GEFIRIX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Carbamazepine or Phenytoin (for the treatment of epilepsy).
- Rifampicin (for treatment of tuberculosis).
- Barbiturates (a type of medicine used for sleeping disorders).
- Herbal remedies containing St John's wort (Hypericum perforatum, used for treatment of depression and anxiety).
- Proton-pump inhibitors, H_2-antagonists and antacids (for the treatment of ulcers, indigestion, heartburn and to reduce acids in the stomach).
- Warfarin (to prevent the forming of blood clots). If you are taking this medicine, your doctor may need to do blood tests regularly.
- Vinorelbine (for the treatment of several types of cancers).
- Ketoconazole, posaconazole and voriconazole (for the treatment of fungal infections).
- Protease inhibitors (Type of antiviral medicines, widely used to treat HIV/AIDS and Hepatitis C).
- Clarithromycin and telithromycin (antibiotics for the treatment of bacterial infections, including infections of the lungs).

Taking GEFIRIX with food and drink

GEFIRIX may be taken by mouth with or without food. The tablet can be swallowed whole with some water or dissolved in half a glass of drinking water (non-fizzy). No other liquids should be used.

Pregnancy, breastfeeding and fertility

Pregnancy

If you are pregnant, think you may pregnant or are planning to have a baby or are breast-feeding, please consult your doctor, pharmacist or other healthcare provider for advice before taking **GEFIRIX**.

It is recommended that you avoid becoming pregnant during treatment with **GEFIRIX** because **GEFIRIX** could harm your baby.

Breast-feeding

For the safety of your baby, do not take **GEFIRIX** if you are breast-feeding.

Driving and using machines

Take care driving, using tools or machinery, if you feel weak whilst taking this medicine.

GEFIRIX contains lactose

Lactose is a source of glucose and galactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **GEFIRIX**.

GEFIRIX contains sodium

GEFIRIX contains less than 1 mmol (23 mg) of sodium per dose, that is to say it is essentially ‘sodium-free’.

3 How to take GEFIRIX

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

Always take **GEFIRIX** exactly as your doctor has told you. Check with your doctor if you are unsure.

- The recommended dose is one 250 mg tablet per day.

- The tablet should be taken at about the same time each day. You can take the tablet with or without food.

If you have trouble swallowing the tablet, **GEFIRIX** may be dissolved in a half a glass of still (non-fizzy) water. Do not use any other liquids. Do not crush the tablet. Swirl the water until the tablet has dissolved (this may take up to 20 minutes). After dissolved, drink the liquid straight away. Rinse the glass very well with half a glass of water and also drink it, to ensure that you have drunk all of the medicine.

If you take more GEFIRIX than you should

If you have taken more **GEFIRIX** than the prescribed dose, contact a doctor immediately. You may experience an increase in occurrence and severity of some side effects, mainly diarrhoea and a skin rash. These symptoms, associated with an overdose, will be treated by your doctor symptomatically.

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

If you forget to take GEFIRIX

What to do if you forget to take a tablet, depends on how long it is until your next dose.

- If it is 12 hours or more until your next dose, take the missed tablet as soon as you remember. Then take the next dose as usual.
- If it is less than 12 hours until the next dose, skip the missed tablet. Take the next tablet at the usual time.
- You should not take a double dose (two doses at the same time) to make up for a forgotten dose.

4 Possible side effects

GEFIRIX can have side effects.

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

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

- Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. This may mean that you have an inflammation of the lungs called ‘interstitial lung disease’. This may be life-threatening.
- Gastrointestinal perforation.
- Allergic reaction (common), particularly if symptoms include swollen face, lips, tongue or throat, difficulty to swallow, hives, nettle rash and difficulty breathing.
- Severe skin reactions (rare) affecting large areas of your body. The signs may include redness, pain, ulcers, blisters, and shedding of the skin. The lips, nose, eyes and genitals may also be affected.

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

- Bleeding, such as a nosebleed or blood found in urine.
- Dehydration (common) caused by long term or severe diarrhoea, vomiting (being sick), nausea (feeling sick) or loss of appetite.

- Inflammation of the liver. Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes).

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:

- Loss of appetite
- Dry, red or itchy eyes
- Red and sore eyelids
- Diarrhoea
- Vomiting
- Nausea
- Swelling, redness, pain or blisters in the mouth
- Dry mouth
- Increase of liver enzymes known as alanine aminotransferase or aspartate aminotransferase, confirmed by a blood test; symptoms include stomach pain, nausea, vomiting, yellow skin or eyes, weakness and tiredness, dark coloured urine.(
- Increase of bilirubin, confirmed with a blood test; symptoms include abdominal pain, chills, fever, chest pain, weakness, tiredness, nausea.
- Skin reactions such as an acne-like rash, which is sometimes itchy with dry and/or cracked skin.
- Nail problems
- Hair loss
- Allergic skin reaction, that may include the following symptoms of the area: painful, itchy, red, welts.

- Increase of creatinine levels in a blood test (related to kidney function). Symptoms include nausea, chest pain, muscle cramps, vomiting, tiredness, high blood pressure, swelling or fluid retention.
- Protein in your urine (shown in a urine test). Symptoms may include foamy, frothy urine and swelling of hands, feet, abdomen or face.
- Cystitis (burning sensations during urination and frequent, urgent need to urinate).
- Abnormal physical weakness or lack of energy.
- Fever

Less frequent side effects:

- Eye pain, eye redness, light sensitivity, blurred vision and tearing, that can all be signs of an ulcer on the surface of your eye (corneal erosion), keratitis (corneal inflammation) or ingrown eyelashes.
- Inflammation of the pancreas. The signs include very severe pain in the upper part of the stomach area and severe nausea and vomiting.
- Inflammation of the blood vessels in the skin. This may give the appearance of bruising or patches of non-blanching rash on the skin.
- Haemorrhagic cystitis (burning sensations during urination and frequent, urgent need to urinate with blood in the urine).

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

Reporting of side effect

If you get side effects, talk to your doctor. 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 **GEFIRIX**.

5 How to store GEFIRIX

- Store all medicines out of reach of children.
- Store at or below 25 °C. Keep in the outer carton until required for use.
- Do not use after the expiry date stated on the label / carton.
- Do not use **GEFIRIX** if you notice any visible signs of deterioration.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Shelf-life

48 months

6 Contents of the pack and other information

What GEFIRIX contains

The active substance is gefitinib.

The other ingredients are: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K-30, purified water and sodium laurilsulfate.

The coating ingredients include Opadry II 85F96667, that consists of iron oxide red, iron oxide yellow, macrogol 3350, polyvinyl alcohol, talc and titanium dioxide.

What GEFIRIX looks like and contents of the pack

GEFIRIX is packed in PVC/PVDC-Aluminum blisters packed in PET/Aluminum pouches. The pouch is further packed in an outer carton.

Pack size: 30 film-coated tablets per carton (10 tablets per blister).

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Proprietary name : Gefirix
Dosage form and strength : Film-coated tablets 250 mg
Approval date : 26 October 2021

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

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