Approved Patient Information Leaflet for ERLOTINIB ZYDUS 25, 100 and 150

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ERLOTINIB ZYDUS 25 film-coated tablets

ERLOTINIB ZYDUS 100 film-coated tablets

ERLOTINIB ZYDUS 150 film-coated tablets

Erlotinib

Contains sugar

Each ERLOTINIB ZYDUS 25 film-coated tablet contains 13,2 mg lactose monohydrate.

Each ERLOTINIB ZYDUS 100 film-coated tablet contains 52,7 mg lactose monohydrate.

Each ERLOTINIB ZYDUS 150 film-coated tablet contains 79,02 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ERLOTINIB ZYDUS

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

What is in this leaflet

1. What ERLOTINIB ZYDUS is and what it is used for

ERLOTINIB ZYDUS contains the active ingredient erlotinib. ERLOTINIB ZYDUS 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.

ERLOTINIB ZYDUS is indicated for adults. ERLOTINIB ZYDUS can be prescribed for you if you have non-small cell lung cancer or adenocarcinoma of your lung at an advanced stage. It can be prescribed as initial therapy of your disease if your cancer cells have specific EFGR 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.

ERLOTINIB ZYDUS can also be prescribed to you in combination with another treatment called gemcitabine if you have cancer of the pancreas at a metastatic stage.

2. What you need to know before you take ERLOTINIB ZYDUS

Do not take ERLOTINIB ZYDUS

If you are hypersensitive (allergic) to erlotinib or to any of the other ingredients of ERLOTINIB ZYDUS listed in section 6 of this leaflet.

Warnings and precautions

Take special care with ERLOTINIB ZYDUS:

- If you are taking other medicines that may increase or decrease the amount of ERLOTINIB ZYDUS in your blood or influence its effect. See ‘Other medicines and ERLOTINIB ZYDUS’.
- If you use contact lenses and/or have a history of eye problems, such as severe dry eyes, inflammation or ulcers in your eye.

You should tell your doctor if you have:

- Sudden difficulty in breathing associated with cough or fever. Your doctor may need to treat you with other medicines and interrupt your ERLOTINIB ZYDUStreatment with ERLOTINIB ZYDUS.
- Diarrhoea. Your doctor may need to treat you with anti-diarrhoeal medicines.
- Severe, bloody or persistent diarrhoea, nausea, loss of appetite or vomiting. You should immediately tell your doctor, as he/she may need to interrupt or stop your treatment with ERLOTINIB ZYDUS and may need to treat you in the hospital.
- Severe pain in the stomach area or a history of diverticular disease or peptic ulceration.
- Severe blistering or peeling of the skin. Your doctor may need to interrupt or stop your treatment with ERLOTINIB ZYDUS.
- Acute or worsening eye problems, such as redness and pain in the eye, increased watering of your eye, blurred vision or sensitivity to light. Your doctor may need to interrupt or stop your treatment with ERLOTINIB ZYDUS.

You should tell your doctor if you are taking statin medicine and experience unexplained muscle pain, tenderness, weakness or cramps while taking ERLOTINIB ZYDUS. Your doctor may need to interrupt your treatment with ERLOTINIB ZYDUS. See ‘Other medicines and ERLOTINIB ZYDUS’.

Treatment with ERLOTINIB ZYDUS is not recommended if you have severe liver disease or severe kidney disease.

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).

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

You are advised to wear protective clothing and/or use sunscreen when you are exposed to the sun during your treatment with ERLOTINIB ZYDUS.

Children and adolescents

ERLOTINIB ZYDUS has not been studied in patients under the age of 18 years. The treatment with ERLOTINIB ZYDUS is not recommended in children and adolescents.

Other medicines and ERLOTINIB ZYDUS

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

Tell your doctor or pharmacist before you take ERLOTINIB ZYDUS if you are taking other medicines that may increase or decrease the amount of ERLOTINIB ZYDUS in your blood or influence its effect, such as:

- Ciprofloxacin, erythromycin or clarithromycin (used to treat certain bacterial infections).
- Fluvoxamine (used to treat depression).
- Ketoconazole, itraconazole or voriconazole (used to treat fungal infections).
- Protease inhibitors (used to treat human immunodeficiency virus (HIV) infection).
- Rifampicin (used to treat tuberculosis (TB)).

- Phenytoin or carbamazepine (used to treat seizures (fits)).
- Barbiturates (used to treat insomnia or anxiety).
- St John's Wort (herbal medicine).
- Omeprazole or ranitidine (used to treat acid reflux).

In some cases, these medicines may reduce the efficacy or increase the side effects of ERLOTINIB ZYDUS and your doctor may need to adjust your treatment.

Tell your doctor or pharmacist before you take ERLOTINIB ZYDUS if you are taking:

- Anticoagulants, such as warfarin (used to prevent blood clots). ERLOTINIB ZYDUS may increase your risk for bleeding and your doctor may need to regularly monitor you with blood tests.
- Statins (a group of medicine used to lower the cholesterol (fat) in your blood). ERLOTINIB ZYDUS may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage.
- Ciclosporin (used to treat psoriasis, rheumatoid arthritis or during organ transplants).
- Verapamil (used to treat high blood pressure or heart problems).
- Capecitabine (used to treat cancer).

ERLOTINIB ZYDUS with food, drink and alcohol

Do not take ERLOTINIB ZYDUS with food. See section 3 "How to take ERLOTINIB ZYDUS'.

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 taking ERLOTINIB ZYDUS.

Avoid pregnancy while being treated with ERLOTINIB ZYDUS. 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 ERLOTINIB ZYDUS, immediately inform your doctor who will decide if treatment should be continued. Do not breastfeed your baby while taking ERLOTINIB ZYDUS.

Driving and using machines

ERLOTINIB ZYDUS is not likely to affect your ability to drive and use machines. However, do not drive a vehicle or operate machinery until you know how ERLOTINIB ZYDUS affects you.

ERLOTINIB ZYDUS contains lactose monohydrate

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

3. How to take ERLOTINIB ZYDUS

Do not share medicines prescribed for you with any other person.
Always take or ERLOTINIB ZYDUS exactly as your doctor or pharmacist has told you. You should 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 ERLOTINIB ZYDUS tablet each day.

Pancreatic cancer

The usual dose is one 100 mg ERLOTINIB ZYDUS tablet each day. ERLOTINIB ZYDUS is given in combination with gemcitabine.

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

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

Do not take ERLOTINIB ZYDUS with a meal. Take your ERLOTINIB ZYDUS 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, ERLOTINIB ZYDUS is available in strengths of 25 mg, 100 and 150 mg.

If you take more ERLOTINIB ZYDUS than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You may have increased side effects and your doctor may interrupt your treatment.

If you forget to take ERLOTINIB ZYDUS

If you forget to take a dose, contact your doctor or pharmacist as soon as possible. Do not take a double dose to make up for a forgotten dose.

If you stop taking ERLOTINIB ZYDUS

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

4. Possible side effects

ERLOTINIB ZYDUS can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

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

Frequent side effects:

- Severe diarrhoea and vomiting (being sick). See also ‘Warnings and precautions’.
- Redness, pain or excessive watering of the eyes, blurred vision, sensitivity to light.
- Gatrointestinal bleeding, causing black stool, stomach cramps, pale skin and vomiting blood.
- Renal insufficiency, causing urinating less than usual, feeling tired, shortness of breath, weakness and an irregular heartbeat.

Less frequent side effects:

- Interstitial lung disease, causing difficulty in breathing associated with a cough or fever.
- Liver failure, causing pain in your upper right stomach area, nausea (feeling sick), vomiting (being sick), yellowing of your skin and whites of your eyes.
- Red and painful blistering and peeling of your skin.
- Gastrointestinal perforation, causing severe pain in your stomach area that worsens when moving.
- Nephritis (causing pain or a burning sensation when you urinate, pain in your pelvis, a

frequent need to urinate or cloudy urine).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection.
- Nose bleeds.
- Changes in blood test results when your doctor tests your liver function.
- Rash, itching, dry skin, cracked skin, acne or small, raised, acne-like bumps on your face, scalp, chest and upper back.
- Hair loss.
- Redness, tenderness and blistering of the skin around your nails, changes in your nails.
- Loss of appetite or decreased weight.
- Difficulty breathing or coughing.
- Nausea (feeling sick), pain in your stomach area, indigestion, flatulence or inflammation of your mouth or lips.
- Neuropathy (altered skin sensation or numbness in the extremities).
- Headaches.
- Depression.
- Excessive tiredness, fever or chills (a sudden feeling of cold with shivering and a rise in temperature).

Less frequent side effects:

- Red, tingling, burning or tender rash with tightness of the skin and thick blisters on the palms of your hands or soles of your feet.
- Changes in eyelashes (such as in-growing eyelashes, excessive growth and thickening) or eyebrows.
- Excess body and facial hair growth.

- Brittle and loose nails, hyperpigmentation (causing dark spots or patches on your skin).
- Protein in your urine.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. 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 ERLOTINIB ZYDUS.

5. How to store ERLOTINIB ZYDUS

- Store at or below 25 °C.
- Keep the blister strip(s) in the outside carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ERLOTINIB ZYDUS contains

The active substance in ERLOTINIB ZYDUS is erlotinib.

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

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

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

The other ingredients are colloidal anhydrous silica (E551), hypromellose (E464), lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), Opadry® white (containing hypromellose (E464), macrogol (E1521), talc (E553b) and titanium dioxide (E171)), polyvinylpolypyrrolidone (E1202) and sodium lauryl sulphate (E487).

What ERLOTINIB ZYDUS looks like and contents of the pack

ERLOTINIB ZYDUS 25: White to off-white, round, film-coated tablets, debossed with '913' on one side and plain on the other side.
ERLOTINIB ZYDUS 100: White to off-white, round, film-coated tablets, debossed with '914' on one side and plain on the other side.
ERLOTINIB ZYDUS 150: White to off-white, round, film-coated tablets, debossed with '915' on one side and plain on other side.

ERLOTINIB ZYDUS is packed in silver OPA/Aluminium/PVC and aluminium blister strips, packed in a cardboard carton.
Pack size: 30 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd
Southdowns Office Park
Building B, Ground Floor
22 Karee Street
Centurion, Pretoria
0157

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