APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ERLOTINIB 25 mg ADCO (film-coated tablets)

ERLOTINIB 100 mg ADCO (film-coated tablets)

ERLOTINIB 150 mg ADCO (film-coated tablets)

Each 25 mg film-coated tablet contains 17,66 mg lactose monohydrate.

Each 100 mg film-coated tablet contains 70,65 mg lactose monohydrate.

Each 150 mg film-coated tablet contains 105,98 mg lactose monohydrate.

- 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.
- ADCO ERLOTINIB 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 ADCO ERLOTINIB is and what it is used for

ADCO ERLOTINIB contains the active substance erlotinib.

ADCO 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.

ADCO ERLOTINIB 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. No survival benefit or other clinically relevant effects of the treatment have been demonstrated in patients with EGFR-negative tumours. It can also be prescribed either if your disease remains largely unchanged after initial chemotherapy, or if previous chemotherapy has not helped to stop your disease.

ADCO ERLOTINIB 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 ADCO ERLOTINIB

Do not take ADCO ERLOTINIB:

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

Warnings and precautions

Special care should be taken with ADCO ERLOTINIB:

- 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 treatment with ADCO ERLOTINIB
- if you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal medicines (for example loperamide)
- if you have severe or persistent diarrhoea, nausea, loss of appetite, or vomiting because your doctor may need to interrupt your ADCO ERLOTINIB 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 with ADCO ERLOTINIB
- if you develop acute or worsening redness and pain in the eyes, increased eye watering, blurred vision and/

or sensitivity to light as you may need urgent treatment.

- If you are exposed to the sun. Wear protective clothing and/ or use sunscreen (e.g. mineral-containing).

It is not known whether ADCO ERLOTINIB has a different effect if your liver or kidneys are not functioning normally. The treatment with ADCO ERLOTINIB is not recommended if you have a 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 ADCO ERLOTINIB as smoking considerably decreases the amount of ADCO ERLOTINIB available in your blood and as efficacy has not been shown in patients who continue to smoke or who have smoked.

Children and adolescents

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

Other medicines and ADCO ERLOTINIB

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

- if you are taking other medicines that may increase or decrease the amount of erlotinib in your blood or influence its effect (for example medicines like ketoconazole, itraconazole, voriconazole, protease inhibitors, erythromycin, clarithromycin, phenytoin, carbamazepine, barbiturates, rifampicin, ciprofloxacin, fluvoxamine, 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 ADCO ERLOTINIB and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines

while you are receiving ADCO ERLOTINIB.

- if you are taking warfarin, ADCO ERLOTINIB may increase your tendency to bleed. Talk to your doctor, he will need to regularly monitor you with blood tests.
- if you are taking statins (medicines to lower your blood cholesterol), ADCO ERLOTINIB may increase the risk of statin related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage.
- if you are taking medicines called P-glycoprotein inhibitors e.g. ciclosporin and verampanil
- if you are taking antacids, the use of medicines altering the pH of your stomach is not recommended and should be avoided.

  If the use of antacids is considered necessary during treatment with ADCO ERLOTINIB, they should be taken at least 4 hours before or 2 hours after the daily dose of ADCO ERLOTINIB.

  If the use of ranitidine is considered, it should be used in a staggered manner, i.e. ADCO ERLOTINIB must be taken at least 2 hours before or 10 hours after the ranitidine dosing. Your doctor will divide your ranitidine dose into 2 equal doses per day.

Your doctor will monitor you closely if you are being treated with any other cancer madicines e.g. carboplatin, paclitaxel, capcitabine or bortezomib.

ADCO ERLOTINIB with food and drink

Do not take ADCO ERLOTINIB with food. See also section 3 ‘How to take ADCO ERLOTINIB’. ADCO ERLOTINIB should be taken at least one hour before or two hours after the ingestion of food.

Pregnancy, breastfeeding and fertility

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 ADCO ERLOTINIB. Do not use ADCO ERLOTINIB if you are pregant and avoid pregnancy while being treated with ADCO ERLOTINIB. If you are able to become pregnant, use adequate contraception during treatment, and for at

least 2 weeks after taking the last tablet.

If you become pregnant while you are being treated with ADCO ERLOTINIB, immediately inform your doctor.

Do not breastfeed if you are being treated with ADCO ERLOTINIB and for at least 2 weeks after the final dose, because of the potential harm to your baby.

The potential effects of ADCO ERLOTINIB on your fertility is unknown.

Driving and using machines

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

Eye disorders have been observed with ADCO ERLOTINIB treatment. This can affect your vision and your ability to drive and safely use macines.

It is not always possible to predict to what extent ADCO ERLOTINIB 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 ADCO ERLOTINIB affects them.

ADCO ERLOTINIB contains lactose monohydrate

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

3. How to take ADCO ERLOTINIB

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

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

Your doctor will tell you how long your treatment with ADCO ERLOTINIB will last. If you have the impression that the effect of ADCO ERLOTINIB is too strong or too weak, tell your doctor or pharmacist.

Your treatment will be supervised by a medical practitioner experienced in the use of anticancer therapies.

Do not take ADCO ERLOTINIB with a meal. Take your ADCO ERLOTINIB 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.

Non-small cell lung cancer: The usual dose is one 150 mg ADCO ERLOTINIB tablet each day.
Pancreatic cancer: The usual dose is one tablet of ERLOTINIB 100 mg ADCO each day. ADCO ERLOTINIB is given in combination with gemcitabine treatment.

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

If you take more ADCO ERLOTINIB 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 ADCO ERLOTINIB

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

If you stop taking ADCO ERLOTINIB

It is important to keep taking ADCO ERLOTINIB every day, as long as your doctor prescribes it for you.

4. Possible side effects

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

If any of the following happens, stop taking ADCO ERLOTINIB immediately and go to the casualty department of your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- blistering of the skin and mucous membranes, shedding of the skin, a spreading skin rash, skin pain, swelling of the face and tongue, are all possible indicators of a rare but very serious skin condition called Steven Johnson's syndrome which requires immediate medical attention.

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

Tell your doctor immediately if you notice any of the following:

- severe or persistent diarrhoea
- difficulty in breathing associated with cough or fever which may be caused by interstitial lung disease, a form of lung irritation that can also be
  linked to the natural progression of your medical condition and can have a fatal outcome in some cases.
- severe pain in the abdomen which can be caused by bleeding from the stomach or intestine.
- liver failure (hepatic failure), which is characterised by yellowing of your skin and yes along with stomach pain and swelling.

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

Tell your doctor if you notice any of the following side effects that may occur frequently:

- Infections
- Loss of apetite and weight decrease
- Redness, itching and tearing and discharge from the eyes (conjunctivitis)
- Dry, red and inflamed eyes
- Eye redness, pain and blurred or decreased vision (keratitis)
- Depression

- Numbness and weakness (a pins-and-needles sensation)
- Headache
- Breathing difficulties and coughing
- Nose bleeds
- Diarrhoea
- Nausea and vomiting
- Inflammation of the membranes in your mouth
- Abdominal pain, indigestion and flatulence
- Liver function test abnormalities
- Rash (mild to moderate), itching and dry skin
- Hair loss
- Infection of the skin surrounding a finger or toenail caused by bacteria or fungi (paronychia).
- Infection of hair follicles.
- Acne
- Cracked skin (skin fissures).
- Kidney problems
- Fatigue, fever and chills

Tell your doctor if you notice any of the following side effects that may occur less frequently:

- Dizziness, trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg
- Eyelash changes
- Painfull eyes, blurred vision, feeling of something in the eye, redness or watery eyes. This may indicate problems with your cornea.
- Inflammation of the uvea (middle layer of the eye) which causes redness, pain and blurred vision.
- Excessive hairiness on woman in those parts of the body where hair does not normally occur or is minimal e.g. facial hair (hirsutism).

- Eyebrow changes
- Brittle and loose nails
- Mild skin reactions such as hyperpigmentation (discolouration)
- Flushed or painful palms or soles (Palmar plantar erythrodysaesthesia syndrome).
- Kidney pain and urination abnormalities, protein in the 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, pharmacist or nurse. You can also report side effects to SAHPRA at https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZA

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

5. How to store ADCO ERLOTINIB:

Store all medicines out of reach of children.

Store at or below 25 °C. Store in the original packaging until required for use.

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 ADCO ERLOTINIB contains

The active substance is erlotinib. Each film-coated tablet contains 25 mg, 100 mg or 150 mg of erlotinib (as erlotinib hydrochloride) depending on the strength.

The other ingredients are:

Tablet core: Lactose monohydrate, cellulose microcrystalline, calcium hydrogen phosphate anhydrous, sodium starch glycolate, silica colloidal anhydrous, sodium laurilsulfate, magnesium stearate (see also section 2 for lactose monohydrate).

Tablet coat: hypromellose, hydroxypropylcellulose, titanium dioxide and macrogol.

What ADCO ERLOTINIB looks like and contents of the pack

ERLOTINIB 25 mg ADCO: White, round biconvex tablet with "E9OB" debossed on one side and "25" on the other. The tablets have a diameter of approximately 6 mm.

ERLOTINIB 100 mg ADCO: White, round, biconvex tablets with a score line on both sides, on one side the tablet is debossed with "E9OB" above the score line and "100" below the score line. The tablets have a diameter of approximately 10 mm. The tablet can be divided into equal halves, each containing 50 mg erlotinib.

ERLOTINIB 150 mg ADCO: White, round, biconvex tablets with "E9OB" debossed in one side and "150" in the other. The tablets have a diameter of approximately 10.4 mm.

ADCO ERLOTINIB tablets are provided in OPA/Alu/PVC and Alu (Alu/Alu) blister strips, packed into a carton.

Pack size: 30 tablets.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

www.adcock.com

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

To be allocated

Registration/Application number

ERLOTINIB 25 mg ADCO: 54/26/0808

ERLOTINIB 100 mg ADCO: 54/26/0809

ERLOTINIB 150 mg ADCO: 54/26/0810

Access to the corresponding Professional Information