

## APPROVED PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S4

**EXONEO 25 mg** (film-coated tablets)

**EXONEO 100 mg** (film-coated tablets)

**EXONEO 150 mg** (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.
- EXONEO 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 EXONEO is and what it is used for
2. What you need to know before you take EXONEO
3. How to take EXONEO
4. Possible side effects
5. How to store EXONEO
6. Contents of the pack and other information

### **1. What EXONEO is and what it is used for**

EXONEO contains the active substance erlotinib.

EXONEO 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.

EXONEO 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.

EXONEO 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 EXONEO**

### **Do not take EXONEO:**

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

### **Warnings and precautions**

#### **Special care should be taken with EXONEO:**

- 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 EXONEO
- 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 EXONEO 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 EXONEO
- 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 EXONEO has a different effect if your liver or kidneys are not functioning normally.

The treatment with EXONEO 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 EXONEO as smoking considerably decreases the amount of EXONEO available in your blood and as efficacy has not been shown in patients who continue to smoke or who have smoked.

### **Children and adolescents**

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

### **Other medicines and EXONEO**

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 EXONEO and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving EXONEO.

- if you are taking warfarin, EXONEO 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), EXONEO 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 verapamil
- 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 EXONEO, they should be taken at least 4 hours before or 2 hours after the daily dose of EXONEO.

If the use of ranitidine is considered, it should be used in a staggered manner, i.e. EXONEO 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 medicines e.g. carboplatin, paclitaxel, capecitabine or bortezomib.

### **EXONEO with food and drink**

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

Do not use EXONEO if you are pregnant and avoid pregnancy while being treated with EXONEO. 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 EXONEO, immediately inform your doctor.

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

The potential effects of EXONEO on your fertility is unknown.

### **Driving and using machines**

EXONEO 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 EXONEO treatment. This can affect your vision and your ability to drive and safely use machines.

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

### **EXONEO contains lactose monohydrate**

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

## **3. How to take EXONEO**

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

Always take EXONEO 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 EXONEO will last. If you have the impression that the effect of EXONEO 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 EXONEO with a meal. Take your EXONEO 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 EXONEO tablet each day.

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

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

### **If you take more EXONEO 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 EXONEO**

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

### **If you stop taking EXONEO**

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

## **4. Possible side effects**

EXONEO can have side effects.

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

If any of the following happens, stop taking EXONEO 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 EXONEO.

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 appetite 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
- Painful 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 erythrodysesthesia 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 EXONEO.

### **5. How to store EXONEO:**

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 EXONEO 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 EXONEO looks like and contents of the pack**

EXONEO 25 mg: White, round biconvex tablet with “E9OB” debossed on one side and “25” on the other.

The tablets have a diameter of approximately 6 mm.

EXONEO 100 mg: 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.

EXONEO 150 mg: 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.

EXONEO 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](http://www.adcock.com)

Customer Care: 0860 ADCOCK / 232625

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To be allocated

**Registration/Application number**

EXONEO 25 mg: 54/26/0805

EXONEO 100 mg: 54/26/0806

EXONEO 150 mg: 54/26/0807

**Access to the corresponding Professional Information**