

## **Bijsluiter: informatie voor de gebruiker**

**Fokleros 100 mg, filmomhulde tabletten**  
**Fokleros 150 mg, filmomhulde tabletten**  
erlotinib

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

#### **1 What [Product name] is and what it is used for**

[Product name] contains the active substance erlotinib. [Product name] 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.

[Product name] is indicated for adults. This medicine can be prescribed to you if you have non-small cell lung cancer at an advanced stage. It can be prescribed as initial therapy or as therapy if your disease remains largely unchanged after initial chemotherapy, provided your cancer cells have specific EGFR mutations. It can also be prescribed if previous chemotherapy has not helped to stop your disease.

This medicine 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 [Product name]**

##### **Do not take [Product name]:**

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

## Warnings and precautions

Talk to your doctor before using [Product name]:

- 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 [Product name] and your doctor may need to adjust your treatment. Your doctor might avoid treating you with these medicines while you are receiving [Product name].
- if you are taking anticoagulants (a medicine which helps to prevent thrombosis or blood clotting e.g. warfarin), [Product name] 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), [Product name] 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.

See also below “Other medicines and [Product name]”

Talk to your doctor:

- 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 [Product name] treatment.
- if you have diarrhoea because your doctor may need to treat you with anti-diarrhoeal (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 [Product name] treatment and may need to treat you in the hospital.
- if you have ever had problems with your liver. Erlotinib may cause serious liver problems and some cases have been fatal. Your doctor may perform blood tests while you are taking this medicine to monitor whether your liver functions properly.
- 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 [Product name] has a different effect if your liver or kidneys are not functioning normally. The treatment with this medicine is not recommended if you have a severe liver disease or severe kidney disease.

#### Glucuronidation disorder like Gilbert's syndrome

Your doctor must treat you with caution if you have a glucuronidation disorder like Gilbert's syndrome.

#### Smoking

You are advised to stop smoking if you are treated with [Product name] as smoking could decrease the amount of your medicine in the blood.

#### **Children and adolescents**

[Product name] has not been studied in patients under the age of 18 years. The treatment with this medicine is not recommended for children and adolescents.

#### **Other medicines and [Product name]**

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

#### **[Product name] with food and drink**

Do not take [Product name] with food. See also section 3 "How to take [Product name]"

#### **Pregnancy and breast-feeding**

Avoid pregnancy while being treated with [Product name]. If you could 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 [Product name], immediately inform your doctor who will decide if the treatment should be continued.

Do not breast-feed if you are being treated with [Product name], and for at least 2 weeks after taking the last tablet.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Driving and using machines**

[Product name] has not been studied for its possible effects on the ability to drive and use machines but it is very unlikely that your treatment will affect this ability.

#### **[Product name] contains lactose monohydrate**

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

#### **[Product name] contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

### **3 How to take [Product name]**

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

The tablet should be taken at least one hour before or two hours after the ingestion of food.

The usual dose is one tablet of [Product name] 150 mg each day if you have non-small cell lung cancer. The usual dose is one tablet of [Product name] 100 mg each day if you have metastatic pancreatic cancer. [Product name] is given in combination with gemcitabine treatment. Your doctor may adjust your dose in 50 mg steps. For the different dose regimens [Product name] is available in strengths of 100 mg or 150 mg.

[Product name] 100 mg, the tablet can be divided into equal doses.

**If you take more [Product name] than you should**

Contact your doctor or pharmacist immediately. You may have increased side effects and your doctor may interrupt your treatment.

**If you forget to take [Product name]**

If you miss one or more doses of [Product name], 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 [Product name]**

It is important to keep taking [Product name] every day, as long as your doctor prescribes it for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact your doctor as soon as possible if you suffer from any of the below side effects. In some cases your doctor may need to reduce your dose of [Invented name] or interrupt treatment:

- Diarrhoea and vomiting (very common: may affect more than 1 in 10 people). 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. If you experience more severe or persistent diarrhoea **contact your doctor immediately** as your doctor may need to treat you in the hospital.
- Eye irritation due to conjunctivitis/keratoconjunctivitis (very common: may affect more than 1 in 10 people) and keratitis (common: may affect up to 1 in 10 people).
- Form of lung irritation called interstitial lung disease (uncommon in European patients; common in Japanese patients: may affect up to 1 in 100 people in Europe and up to 1 in 10 in Japan). This disease can also be linked to the natural progression of your medical condition and can have a fatal outcome in some cases. If you develop symptoms such as sudden difficulty in breathing associated with cough or fever contact your doctor immediately as you could suffer from this disease. Your doctor may decide to permanently stop your treatment with [Invented name].
- Gastrointestinal perforations have been observed (uncommon: may affect up to 1 in 100 people). Tell your doctor if you have severe pain in your abdomen. Also, tell your doctor if you had peptic ulcers or diverticular disease in the past, as this may increase this risk.

- In rare cases inflammation of the liver (hepatitis) was observed (rare: may affect up to 1 in 1,000 people). Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes), dark urine, nausea, vomiting and abdominal pain. In rare cases liver failure was observed. This can potentially be fatal. If your blood tests indicate severe changes in your liver function, your doctor may need to interrupt your treatment.

**Very common side effects** (may affect more than 1 in 10 people):

Rash which may occur or worsen in sun exposed areas. If you are exposed to sun, protective clothing, and/or use of sun screen (e.g. mineral-containing) may be advisable • Infection • Loss of appetite, decreased weight • Depression • Headache, altered skin sensation or numbness in the extremities • Difficulty in breathing, cough • Nausea • Mouth irritation • Stomach pain, indigestion and flatulence • Abnormal blood tests for the liver function • Itching, dry skin and loss of hair • Tiredness, fever, rigors.

**Common side effects** (may affect up to 1 in 10 people):

Bleeding from the nose • Bleeding from the stomach or the intestines • Inflammatory reactions around the fingernail • Infection of hair follicles • Acne • Cracked skin (skin fissures) • Reduced kidney function (when given outside the approved indications in combination with chemotherapy).

**Uncommon side effects** (may affect up to 1 in 100 people):

Eyelash changes • Excess body and facial hair of a male distribution pattern • Eyebrow changes • Brittle and loose nails.

**Rare side effects** (may affect up to 1 in 1,000 people):

Flushed or painful palms or soles (Palmar plantar erythrodysesthesia syndrome).

**Very rare side effects** (may affect up to 1 in 10,000 people):

Cases of perforation or ulceration of the cornea • Severe blistering or peeling of skin (suggestive of Stevens-Johnson syndrome) • Inflammation of the coloured part of the eye.

**Reporting of side effects**

If you get any 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 directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store {Product name}**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6 Contents of the pack and other information**

### **What [Product name] contains**

- The active substance is erlotinib. Each film-coated tablet contains 100 mg or 150 mg of erlotinib (as erlotinib hydrochloride) depending on the strength.
- The other ingredients are:  
Tablet core: lactose monohydrate; cellulose, microcrystalline and calcium hydrogen phosphate anhydrous; sodium starch glycolate; silica, colloidal anhydrous; cellulose, microcrystalline (E460); sodium laurilsulfate; magnesium stearate (E470 b)  
Tablet coating: hypromellose (E464); hydroxypropylcellulose (E463); titanium dioxide (E171); macrogol

### **What [Product name] looks like and contents of the pack**

[Invented name] 100 mg is a white, round, biconvex tablet 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, with a diameter of approximately 10 mm. The tablet can be divided into equal doses.

[Invented name] 150 mg is a white, round, biconvex tablet with “E9OB” debossed on one side and “150” on the other, with a diameter of approximately 10.4 mm

[Invented name] is available in blister containing 30 tablets.  
Each carton box contains 30 tablets.

### **Houder van de vergunning voor het in de handel brengen en fabrikant**

ALKALOID-INT d.o.o.  
Šlandrova Ulica 4,  
1231 Črnuče, Ljubljana,  
Slovenië

### **Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:**

Fokleros 100 mg, filmomhulde tabletten    RVG 123051  
Fokleros 150 mg, filmomhulde tabletten    RVG 123052

**Deze bijsluiter is voor het laatst goedgekeurd in februari 2023.**