Package leaflet: Information for the user

Gefitinib Eugia 250 mg filmomhulde tabletten
gefitinib

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 any 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 <Invented name> is and what it is used for

<Invented name> contains the active substance gefitinib which blocks a protein called 'epidermal growth factor receptor' (EGFR). This protein is involved in the growth and spread of cancer cells.

<Invented name> 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 <Invented name>

Do not take <Invented name>
- if you are allergic to <Invented name> or any of the other ingredients of this medicine (listed in section 6, 'What <Invented name> contains').
- if you are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name>.
- if you have ever had any other lung problems. Some lung problems may get worse during treatment with <Invented name>.
- if you have ever had problems with your liver.

Children and adolescents
<Invented name> is not indicated in children and adolescents under 18 years.

Other medicines and <Invented name>

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Phenytoin or carbamazepine (for epilepsy).
- Rifampicin (for tuberculosis).
- Itraconazole (for fungal infections).
- Barbiturates (a type of medicine used for sleeping problems).
- Herbal remedies containing St John's wort (*Hypericum perforatum*, used for depression and anxiety).
- Proton-pump inhibitors, H2-antagonists and antacids (for ulcers, indigestion, heartburn and to reduce acids in the stomach).
- These medicines may affect the way <Invented name> works.
- Warfarin (a so-called oral anticoagulant, to prevent blood clots). If you are taking a medicine containing this active substance, your doctor may need to do blood tests more often.
- If any of the above applies to you, or if you are not sure, check with your doctor or pharmacist before taking <Invented name>.

Pregnancy, breast-feeding and fertility
Talk to your doctor before taking this medicine if you are pregnant, may become pregnant or are breast-feeding.
It is recommended that you avoid becoming pregnant during treatment with <Invented name> because <Invented name> could harm your baby.
Do not take <Invented name> if you are breast-feeding. This is for the safety of your baby.

Driving and using machines
You may feel weak while taking treatment with <Invented name>. If this happens, do not drive or use any tools or machines.

<Invented name> contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

<Invented name> contains sodium
This medicine contains less than 1 mmol (23 mg) of sodium per dose, that is to say it is essentially 'sodium-free'.

3. How to take <Invented name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The recommended dose is one 250 mg tablet per day.
- Take the tablet at about the same time each day.
- You can take the tablet with or without food.
- Do not take antacids (to reduce the acid level of your stomach) 2 hours before or 1 hour after taking <Invented name>.

The tablet may be taken orally with or without food, at about the same time each day.

Administration through water:
The tablet can be swallowed whole with some water or if dosing of whole tablets is not possible, tablets may be administered as a dispersion in water (non-carbonated). No other liquids should be used. Without crushing it, the tablet should be dropped in half a glass of drinking water. The glass should be swirled occasionally, until the tablet is dispersed (this may take up to 20 minutes). The dispersion should be drunk immediately after dispersion is complete (i.e. within 60 minutes). The glass should be rinsed with half a glass of water, which should also be drunk.

Administration through naso-gastric or gastrostomy tube:
The above dispersion can also be administered through a naso-gastric or gastrostomy tube.

Instruction for administration through enteral tubes:

- Drop the tablet in half glass of drinking water (non-carbonated).
- Swirl the solution until the tablet is dispersed (this may take around 20 minutes).
- It is important that dispersion is complete before administration through a naso-gastric or gastrotomy tube.
- Administer in a French size 8 tube or larger (inner diameter ≥ 1.5 mm).
- Administer within 60 minutes after preparation.
- Rinse the glass with drinking water and then flush the enteral tube.

Special precautions for caregivers and healthcare professionals regarding occupational exposure to toxic substances.

If you take more <Invented name> than you should

If you have taken more tablets than you should, talk to a doctor or pharmacist straight away.

If you forget to take <Invented name>.
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 your next dose: skip the missed tablet. Then take the next tablet at the usual time.

Do not take a double dose (two tablets at the same time) to make up for a forgotten dose.

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.

Tell your doctor immediately if you notice any of the following side effects - you may need urgent medical treatment:
- Allergic reaction (common), particularly if symptoms include swollen face, lips, tongue or throat, difficulty to swallow, hives, nettle rash and difficulty breathing.
- 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 affect about 1 in 100 patients taking <Invented name>and can be life-threatening.

- 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.
- Dehydration (common) caused by long term or severe diarrhoea, vomiting (being sick), nausea (feeling sick) or loss of appetite.
- Eye problems (uncommon), such as pain, redness, watery eyes, light sensitivity, changes in vision or ingrowing eyelashes. This may mean that you have an ulcer on the surface of the eye (cornea).

Tell your doctor as soon as possible if you notice any of the following side effects:

Very common: **may affect more than 1 in 10 people**
- Diarrhoea
- Vomiting
- Nausea
- Skin reactions such as an acne-like rash, which is sometimes itchy with dry and/or cracked skin
- Loss of appetite
- Weakness
- Red or sore mouth
- Increase of a liver enzyme known as alanine aminotransferase in a blood test; if too high, your doctor may tell you to stop taking <Invented name>

Common: may affect up to 1 in 10 people
- Dry mouth
- Dry, red or itchy eyes
- Red and sore eyelids
- Nail problems
- Hair loss
- Fever
- Bleeding (such as nose bleed or blood in your urine)
- Protein in your urine (shown in a urine test)
- Increase of bilirubin and the other liver enzyme known as aspartate aminotransferase in a blood test; if too high, your doctor may tell you to stop taking <Invented name>
- Increase of creatinine levels in a blood test (related to kidney function)
- Cystitis (burning sensations during urination and frequent, urgent need to urinate)

Uncommon: may affect up to 1 in 100 people
- 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 liver. Symptoms may include a general feeling of being unwell, with or without possible jaundice (yellowing of the skin and eyes). This side effect is uncommon; however, some patients have died from this.
- Gastrointestinal perforation
- Skin reaction on the palms of the hands and soles of the feet including tingling, numbness, pain, swelling or reddening (known as palmar-plantar erythrodysaesthesia syndrome or hand and foot syndrome).

Rare: may affect up to 1 in 1000 people
- 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).

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 <Invented 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 packaging 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 waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

- The active substance is gefitinib. Each film-coated tablet contains 250 mg of gefitinib.

- The other ingredients are:
  Tablet core: lactose monohydrate, cellulose microcrystalline (Grade-101), croscarmellose sodium, povidone (K-30), sodium laurylsulfate, magnesium stearate
  Tablet coating: Polyvinyl Alcohol (Part Hydrolyzed), Macrogol 4000, talc, iron oxide red, iron oxide yellow, titanium dioxide.

What <Invented name> looks like and contents of the pack
Film-coated tablet

<Invented name> is Brown colored, round, approximately 11mm, biconvex, film-coated tablet debossed with “G 250” on one side and plain on the other side.

<Invented name> film-coated tablets are available in blister pack with 30 film-coated tablets.

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

Vergunninghouder:
Eugia Pharma (Malta) Limited
Vault 14, Level 2
Valletta Waterfront
Floriana, FRN 1914
Malta

Voor correspondentie en inlichtingen:
Aurobindo Pharma B.V.
Baarnsche Dijk 1
3741 LN Baarn
Nederland

Fabrikant:
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

Generis Farmacêutica, S.A.
Rua João de Deus, nº 19, Venda Nova
2700-487 Amadora
Portugal

In het register ingeschreven onder:

Gefitinib Eugia 250 mg filmomhulde tabletten RVG 129222

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

Malta: Gefitinib Eugia 250 mg film-coated tablets
Netherland: Gefitinib Eugia 250 mg filmomhulde tabletten
Portugal: Gefitinib Eugia
Spain: Gefitinib Eugia 250 mg comprimidos recubiertos con película EFG

Deze bijsluiter is voor het laatst goedgekeurd in januari 2026.