

GEFISSET 250 FILM-COATED TABLET

Gefitinib (250mg)

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What Gefiset 250 is used for

Gefiset 250 is used to treat advanced non- small cell lung cancer, which is one type of lung cancer.

How Gefiset 250 works

Gefiset 250 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.

Before you use Gefiset 250

- When you must not use it

Do not take **Gefiset 250** if you are allergic to gefitinib or any of the other ingredients of **Gefiset 250**, listed at the end of this leaflet. If you think you may be allergic, ask your doctor for advice.

Gefiset 250 is not recommended for use in children or adolescents.

- Before you start to use it

Before taking **Gefiset 250**, tell your doctor:

- if you have or have had any other lung diseases, other than your lung cancer. Some of them may worsen during treatment with **Gefiset 250**.
- if you are pregnant or trying to become pregnant. You should avoid becoming pregnant during treatment with **Gefiset 250**.
- if you are breast-feeding. For the safety of your baby, you should discontinue breast-feeding during treatment with **Gefiset 250**.

- Taking other medicines

Please inform your doctor if you are taking or have taken any medicines (including medicines taken some time

ago), even those not prescribed. Your doctor especially needs to know:

- if you take any of the following medicines:
phenytoin, carbamazepine, rifampicin, barbiturates, St John's Wort or itraconazole, or any medicines that reduce the acidity on your stomach, such as ranitidine. These medicines may affect the way **Gefiset 250** works.
- if you take warfarin (to prevent blood-clots), as **Gefiset 250** may affect it. Your doctor may need to check your blood more often.

How to use Gefiset 250

- How much to use & When to use it

Take one 250 mg tablet, once a day, every day about the same time. You can take **Gefiset 250** with or without food.

For individuals who are only able to swallow liquids, the tablet may be used as a dispersion in water. The tablet should be dropped into half a glass of drinking water (non-carbonated), without crushing, and the glass stirred until the tablet has dispersed (approximately 15 minutes) and the contents subsequently drunk immediately. The glass should be rinsed with a further half glass of water and the contents drunk.

The liquid can also be used via a nasogastric tube.

- How long to use it

Take **Gefiset 250** as directed by your healthcare provider.

- If you forget to use it

If you forget to take a dose, take the last missed dose as soon as you remember, as long as it is at least 12 hours before the next dose is due.

If it is less than 12 hours to the next dose, do not take the dose you have missed. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

- If you use too much (overdose)

If you take more than the recommended number of tablets, contact a doctor or pharmacist immediately. An increase

of frequency and severity of some adverse reactions was observed, mainly diarrhea and skin rash.

While you are using it

- Things you must do

It is important to keep taking **Gefiset 250** as your doctor has told you to. The instructions on the label should remind you of what the doctor has said.

- Things you must not do

Do not stop taking your dose without talking to your healthcare provider.

- Things to be careful of

Driving and using machines

During treatment with **Gefiset 250**, lack of energy and strength has been reported and those people who experience this symptom should observe caution when driving or using machines.

Side effects

Like all medicines, **Gefiset 250** can have side effects. These are usually mild to moderate in intensity. Do not be alarmed by the list of side effects. You may not have any of them.

Contact your doctor without delay if any of the following happens to you, as you may need further examinations or treatment:

- Serious breathlessness, or sudden worsening breathlessness, possibly with a cough or fever. Some individuals taking **Gefiset 250** get an inflammation of the lungs called interstitial lung disease. This side effects is common (about 1 of every 100 people are likely to have it), and some people have died from this.
- Unexpected bleeding, if you are also taking warfarin.
- Some people have suffered from dehydration (1 to 10 of every 100 people) following persistent or severe diarrhoea, vomiting, nausea (feeling sick) or loss of appetite.
- New or worsening eye problems, such as pain, redness, watery eyes, light sensitivity or changes in your vision. Some people have suffered from ulcer on the surface of the eye (cornea), sometimes with

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ingrowing eyelashes; this side effect is uncommon (less than 1 in every 100 people).

- Severe skin reactions affecting large portions of your body including redness, pain, ulcers, blisters, skin sloughing or involvement of lips and mucous membranes (toxic epidermal necrolysis, Stevens Johnson syndrome, erythema multiforme). This type of skin reaction is rare (less than 1 in every 1,000 people is likely to have them).

Tell your doctor if any of the following side effects bothers you:

Very common side effects: may affect more than 10 of every 100 people:

- Diarrhoea.
- Nausea (feeling sick)
- Skin reactions such as an acne-like rash, sometimes itchy with dry and/or cracked skin.
- Vomiting
- Loss of appetite.
- Weakness.
- Red and sore mouth.

Common side effects: may affect up to 1 to 10 of every 100 people

- Dry mouth
- Nail problems
- Loss of hair
- Dry eyes
- Red and sore eyelid
- Nose bleed and blood in your urine
- Fever.
- Protein in your urine (shown in a urine test).
- Cystitis (burning sensations during urination and frequent, urgent need to urinate).
- Allergic reactions, including swelling of lips, face, tongue or throat and hives or nettle-rash

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

- Inflammation of the pancreas with symptoms such as 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 erythrodysesthesia syndrome or hand and foot syndrome).

Rare side effects: may affect up to 1 in 1,000 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

The following side effects can also occur with **Gefiset 250**, and they are seen when a blood test is taken:

- Changes of the levels of liver enzymes and bilirubin. If these levels become very high, your doctor may need to stop the treatment.
 - Changes to the level of one liver enzyme known as alanine aminotransferase (ALT) is very common (more than 10 of every 100 people)
 - Changes to the level of bilirubin and the other liver enzyme known as aspartate aminotransferase (AST) are common (1 to 10 of every 100 people)
- Changes to the level of creatinine in your blood, which show how well your kidneys are working. This side effect is common (1 to 10 of every 100 people).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist as soon as possible.

You may report any side effects or adverse drug reactions directly to the

National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Gefiset 250

- *Storage*

Keep out of the reach and sight of children.

Store below 30°C in the original package.

- *Disposal*

Remember to return any unused **Gefiset 250** to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

Brown, round, biconvex, film-coated tablets, embossed with "G" on one side and plain on the other side.

- *Ingredients*

- Active ingredient: Gefitinib

- Inactive ingredients:

Tablet core

Cellulose microcrystalline, Lactose monohydrate, Crospovidone type A, Povidone K30, Sodium laurilsulfate, Purified water, Cellulose microcrystalline, Sodium starch glycolate Type A, Magnesium stearate.

Film coat

Poly (vinyl alcohol) (E1203), Talc (E553b), Iron oxide red (E172), Glycerol monocaprylocaprate Type 1, Titanium dioxide (E171), Sodium laurilsulfate, Iron oxide yellow (E172), Iron oxide black (E172)

- *MAL number:*

MAL *****

Manufacturer

Genepharm S.A
18th km Marathonos Avenue,
Pallini, 15351, Greece

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Product Registration Holder

Mega Lifesciences Sdn. Bhd.
B-28-02, The Ascent, Paradigm,
No. 1, Jalan SS 7/26A, Kelana Jaya,
47301 Petaling Jaya,
Selangor, Malaysia

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