

GEFITINIB intega FILM-COATED TABLETS

Gefitinib (250mg)

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What *GEFITINIB intega* is used for

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

How *GEFITINIB intega* works

GEFITINIB intega 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 *GEFITINIB intega*

- When you must not use it

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

GEFITINIB intega is not recommended for use in children or adolescents.

- Before you start to use it

Before taking *GEFITINIB intega*:

- 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

GEFITINIB intega.

- Tell your doctor if you are pregnant or trying to become pregnant. You should avoid becoming pregnant during treatment with *GEFITINIB intega*.
- Tell your doctor if you are breast-feeding. For the safety of your baby, you should discontinue breast-feeding during treatment with *GEFITINIB intega*.

- 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 *GEFITINIB intega* works.
- if you take warfarin (to prevent blood-clots), as *GEFITINIB intega* may affect it. Your doctor may need to check your blood more often.

How to use *GEFITINIB intega*

- 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 *GEFITINIB intega* 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 *GEFITINIB intega* 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 *GEFITINIB intega* 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 *GEFITINIB intega*, 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, *GEFITINIB intega* 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 *GEFITINIB intega* get an inflammation of the lungs called interstitial lung disease. This side effect is common and some people have died from this.
- Unexpected bleeding, if you are also taking warfarin.
- Some people have suffered from dehydration 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 ingrowing eyelashes; this side effect is uncommon.
- 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.

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

- Side effects that are very common:
- Diarrhoea
 - Nausea (feeling sick)

- Skin reactions such as acne-like rash, sometimes itchy with dry and/or cracked skin
- Vomiting
- Loss of appetite
- Weakness
- Red and sore mouth

Side effects that are common:

- Dry mouth
- Nail problems
- Loss of hair
- Dry eye
- Red and itchy eye
- 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

Side effects that are uncommon:

- Inflammation of the pancreas, with symptoms such as very severe pain in the upper part of the stomach area and severe nausea (feeling sick) 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 people have died from this.
- Gastrointestinal perforation

Side effects that are rare :

- 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 *GEFITINIB intega*, 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
 - Changes to the level of bilirubin and the other liver enzyme known as aspartate aminotransferase (AST) are common
- Changes to the level of creatinine in your blood, which show how well your kidneys are working. This side effect is common.

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 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 & Disposal of *GEFITINIB intega*

- Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Keep *GEFITINIB intega* in the original container in order to protect from moisture.
- Do not use *GEFITINIB intega* after the expiry date on the blister pack.

- Disposal

- Remember to return any unused *GEFITINIB intega* 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 tablet impressed with '250' on one side and plain on the other side.

Each tablet contains 250 mg gefitinib.

GEFITINIB Intega tablets come in blister packs containing 30 tablets.

- Ingredients

- Active ingredient: gefitinib.

Inactive ingredients: Lactose monohydrate, Microcrystalline cellulose, Croscarmellose Sodium, Povidone, Magnesium stearate, Sodium laurilsulfate, Poly (Vinyl Alcohol), Macrogol 3350, Talc. Titanium dioxide, Red iron oxide, Yellow iron oxide, Purified Water.

- MAL number:

MAL 20106007ACZ

Manufacturer

Remedica Ltd
Aharnon Street,
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3056 Limassol, Cyprus

Product Registration Holder

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