

GENESSA FILM COATED TABLETS

Gefitinib (250mg)

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What Genessa is used for

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

How Genessa works

Genessa 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 Genessa

- When you must not use it

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

Genessa is not recommended for use in children or adolescents.

- Before you start to use it

Before taking Genessa:

- 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 Genessa.
- Tell your doctor if you are pregnant or trying to become

pregnant. You should avoid becoming pregnant during treatment with Genessa.

- Tell your doctor if you are breast-feeding. For the safety of your baby, you should discontinue breast-feeding during treatment with Genessa.

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

How to use Genessa

- 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 Genessa 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.

Genessa tablets must be taken regularly for it to be effective. Continue taking Genessa tablets even if there are signs of improvement. Do not stop taking Genessa tablets unless instructed by your doctor.

- How long to use it

Take Genessa 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 Genessa 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 the treatment without consulting your doctor.

Do not use Genessa tablets to treat any other conditions unless your doctor orders you to.

Do not recommend or give Genessa tablets to anyone else even if they have the same condition as you.

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- Things to be careful of

Driving and using machines

During treatment with Genessa, 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, Genessa 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 Genessa 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
- 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).

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 Genessa, 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 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)]

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Storage & Disposal of Genessa

- Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Do not use Genessa after the expiry date on the blister pack.

- Disposal

- Remember to return any unused Genessa 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

Round, biconvex, brown film-coated tablet debossed with “GEF 250” on one side and plain on other side.

- Ingredients

- Active ingredient
The active substance of Genessa 250mg Film Coated Tablets is 250mg gefitinib.

- Inactive ingredients

Tablet core:

- Lactose Monohydrate
- Microcrystalline Cellulose
- Crospovidone
- Povidone
- Sodium Lauryl Sulfate
- Magnesium Stearate

Film coat:

- Opadry II Complete Film Coating System
85F565317 Brown

- MAL number:

MALXXXXXXXXXX

Manufacturer

Novugen Oncology Sdn. Bhd.
No. 47, Jalan Lengku Teknologi 2,
Taman Teknologi Enstek Fasa 1,
71760 Bandar Baru Enstek,
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Product Registration Holder

Novugen Oncology Sdn. Bhd.
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