

VEIASU FILM-COATED TABLETS

Gefitinib (250mg)

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- becoming pregnant during treatment with Veiasu
- Breastfeeding. For the safety of your baby, you should discontinue breastfeeding during treatment with Veiasu

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

When to use it

You may take Veiasu with or without food. Try to take it at the same time each day. This will help you remember when to take your medicine.

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

What Veiasu is used for

Veiasu is used to treat advanced non-small cell lung cancer (NSCLC), which is a type of lung cancer.

How Veiasu works

Veiasu contains the active substance gefitinib. Gefitinib works by blocking a protein called 'epidermal growth factor receptor' (EGFR). This protein is involved in the growth and spread of cancer cells.

Please inform your doctor if you are taking any of the following medicines:

- Warfarin (to prevent blood clots). Veiasu may affect it. Your doctor may need to check your blood more often.
- Phenytoin, carbamazepine, rifampicin, barbiturates, St John's Wort or itraconazole or any other medicines that reduce the acidity on your stomach, such as ranitidine. These medicines may affect the way Veiasu works.

How long to use it

You should continue to take Veiasu tablets each day as long as prescribed by your doctor. If you have questions on the duration of your treatment, ask your doctor.

If you forget to use it

Take the missed dose as soon as you remember, as long as it is at least 12 hours before the next dose is due.

Before you use Veiasu

When you must not use it

Do not take Veiasu tablets if you are allergic (hypersensitive) to gefitinib or any of the other ingredients of Veiasu tablets (see ingredient list).

Veiasu is not recommended for use in children or adolescents.

Before you start to use it

If you have the following:

- Having or had any other lung diseases (other than your lung cancer). Some of these diseases may worsen during treatment with Veiasu
- Pregnant or trying to be pregnant. You should avoid

How to use Veiasu

How much to use

Take one tablet, once a day, every day about the same time.

If you are only able to swallow liquids, tablets may be administered 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.

However, 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 have taken too much of Veiasu tablets by accident, contact your doctor or hospital immediately for advice. Show them the pack of tablets. A medical treatment may be necessary.

While you are using Veiasu

Things you must do

It is important for you to keep taking Veiasu as your doctor has advised you to.

Things you must not do

Do not stop the treatment without consulting your doctor.

Do not use Veiasu tablets to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Driving and using machines

During treatment with Veiasu, a lack of energy and strength has been reported. People who experienced this symptom should observe caution when driving or using machines.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without a prescription.

Side effects

Like all medicines, Veiasu tablets can cause side effects, although not everybody gets them.

Contact your doctor if any of the following happens to you, as you may need further examinations or treatment:

- Serious breathlessness, or sudden worsening in breathlessness, possibly with a cough or fever. Some individuals taking Veiasu get an inflammation of the lungs called interstitial lung disease. This side effect 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 eye redness, pain, 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 (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:

Side effects that are very common (more than 10 of every 100 people are likely to have them):

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

Side effects that are common (1 to 10 of every 100 people are likely to have them):

- 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 (less than 1 in every 100 people is likely to have them)

- 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 (less than 1 in every 1,000 people is likely to have them)

- 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 Veiasu 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 any of the side effects gets serious, or if you notice any side effects not mentioned here, 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 Veiasu

Storage

Store below 30°C, away from direct sunlight in a cool and dry place. Keep out of the reach of children.

Disposal

Do not use Veiasu tablets after the expiry date which is stated on the label and carton.

If your doctor tells you to stop taking Veiasu tablets or your tablets have passed their expiry date, ask your pharmacist or doctor what to do with any that are left over. Do not simply throw the left over or expired products into the dustbin.

Product Description

What it looks like

Brown, film-coated, round, biconvex tablets, debossed with “LP100” on one side and plain on the other side.

Active ingredient(s)

Active ingredient: Gefitinib.

Inactive ingredients

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone K-30, sodium laurilsulfate, magnesium stearate, Opadry II 85F96667

MAL Number:

MAL22106011AZ

Manufacturer

Lotus Pharmaceutical Co., Ltd,
Nantou Plant
No 30, Chenggong 1st Rd.,
Sinsing Village,
Nantou City,
Nantou County 540033,
Taiwan.

Product Registration Holder

Lotus Healthcare Malaysia
Sdn. Bhd.
UOA Business Park, Tower 3,
9th Floor, K03-09-11,
1 Jalan Pengaturcara U1/51A,
Section U1,
40150 Shah Alam,
Malaysia

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