

ALSUNI CAPSULES

Sunitinib (as Malate) (12.5 mg / 25 mg / 50 mg)

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What ALSUNI is used for

ALSUNI is used to treat adults with the following types of cancer:

- Gastrointestinal stromal tumour (GIST), a type of cancer of the stomach and bowel, after disease progression on or, where imatinib (another anticancer medicine) no longer works or you cannot take imatinib.
- Advanced renal cell carcinoma, a type of kidney cancer that has spread to other parts of the body.
- Pancreatic neuroendocrine tumours (pNET) tumours of the hormone-producing cells in the pancreas that have progressed or cannot be removed with surgery.

How ALSUNI works

ALSUNI is used to treat cancer by preventing the activity of a special group of proteins which are known to be involved in the growth and spread of cancer cells.

Before you use ALSUNI

– When you must not use it

Do not take ALSUNI if you are allergic to sunitinib or any of the other ingredients of this medicine.

– Before you start to use it

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

If you might get pregnant, you should use a reliable method of contraception during treatment with ALSUNI.

If you are breast-feeding, tell your doctor. You should not breastfeed during treatment with ALSUNI.

– Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription and even those not prescribed.

Some medicines can affect the levels of ALSUNI in your body. You should inform your doctor if you are taking medicines containing the following active substances:

- ketoconazole, itraconazole – used to treat fungal infections;
- erythromycin, clarithromycin, rifampicin – used to treat infections;
- ritonavir – used to treat HIV;
- dexamethasone – a corticosteroid used for various conditions (such as allergic/breathing disorders or skin diseases);
- phenytoin, carbamazepine, phenobarbital – used to treat epilepsy and other neurological conditions;
- herbal preparations containing St. John's Wort (*Hypericum perforatum*) – used to treat depression and anxiety.

ALSUNI with food and drink:

You should avoid drinking grapefruit juice while on treatment with ALSUNI.

How to use ALSUNI

– How much to use

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor will prescribe a dose that is right for you, depending on the type of cancer to be treated. If you are being treated for:

- GIST or advanced renal cell carcinoma: the usual dose is 50 mg once daily taken for 28 days (4 weeks), followed by 14 days (2 weeks) of rest (no medicine), in 6-week cycles.
- pNET: the usual dose is 37.5 mg once daily without a rest period.

– When to use it

It can be taken with or without food.

– How long to use it

Your doctor will determine if and when you need to stop treatment with ALSUNI.

If you forget to use it

Do not take a double dose to make up for a forgotten dose.

– If you use too much (overdose)

If you have accidentally taken too many capsules, talk to your doctor straight away. You may require medical attention.

While you are using it

– Things you must do

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you have symptoms such as lack of energy, confusion, sleepiness, unconsciousness/coma, your doctor will measure your ammonia level and determine appropriate treatment because these may be signs of brain toxicity caused by high blood levels of ammonia (hyperammonaemic encephalopathy).

– Things you must not do

Do not stop taking ALSUNI unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give ALSUNI to anyone else, even if they have the same symptoms or condition as you.

– Things to be careful of

Talk to your doctor before taking ALSUNI if you:

- have high blood pressure.
- have or have had blood disease, bleeding problems, or bruising.
- have heart problems.
- have abnormal heart rhythm changes.
- have had a recent problem with blood clots in your veins and/or arteries (types of blood vessels), including stroke, heart attack, embolism, or thrombosis.
- have or have had an aneurysm (enlargement and weakening of a

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- blood vessel wall) or a tear in a blood vessel wall.
- have or have had damage to the smallest blood vessels known as thrombotic microangiopathy (TMA).
- have thyroid glands problems.
- have or have had pancreatic or gallbladder disorders.
- have or have had liver problems.
- have or have had kidney problems.
- are going to have surgery or if you had an operation recently.
- you may be advised to have a dental check-up before you start treatment with ALSUNI.
- have or have had skin and subcutaneous tissue disorders
- have or have had seizures.
- have diabetes.

Driving and using machines

If you experience dizziness or you feel unusually tired, take special care when driving or using machines.

Side effects

Like all medicines, ALSUNI can cause side effects, although not everybody gets them. You must immediately contact your doctor if you experience any of those serious side effects after taking this medicine:

- Heart problems.
- Lung or breathing problems.
- Kidney disorders.
- Bleeding.
- Tumour destruction leading to hole in the intestine. (Tell your doctor if you have severe abdominal pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits).

Other side effects with ALSUNI may include:

Very common:

- Reduction in the number of platelets, red blood cells and/or white blood cells (e.g., neutrophils).
- Shortness of breath.

- High blood pressure.
- Extreme tiredness, loss of strength.
- Swelling caused by fluid under the skin and around the eye, deep allergic rash.
- Mouth pain/irritation, mouth sores/inflammation/dryness, taste disturbances, upset stomach, nausea, vomiting, diarrhoea, constipation, abdominal pain/swelling, loss/decrease of appetite.
- Decreased activity of thyroid gland (hypothyroidism).
- Dizziness.
- Headache.
- Nose bleeding.
- Back pain, joint pain.
- Pain in arms and legs.
- Yellow skin/skin discoloration, excess pigmentation of the skin, hair colour change, rash on the palms of the hands and soles of the feet, rash, dryness of the skin.
- Cough.
- Fever.
- Difficulty in falling asleep.

Common:

- Blood clots in the blood vessels.
- Deficiency of blood supply to the heart muscle, due to obstruction or constriction of the coronary arteries.
- Chest pain.
- Decrease in the amount of blood pumped by the heart.
- Fluid retention including around the lungs.
- Infections.
- Complication of severe infection (infection is present in the bloodstream) that can lead to tissue
- Damage, organ failure, and death.
- Decreased blood sugar level.
- Loss of protein in the urine sometime resulting in swelling.
- Influenza-like syndrome.
- Abnormal blood tests including pancreatic and liver enzymes.
- High level of uric acid in the blood.
- Haemorrhoids, pain in the rectum, gingival bleeding, difficulty in

swallowing or inability to swallow.

- Burning or painful sensation in the tongue, inflammation of the digestive tract lining, excessive gas in the stomach or intestine.
- Weight loss.
- Musculoskeletal pain (pain in muscles and bones), muscular weakness, muscular fatigue, muscle pain, muscle spasms.
- Nasal dryness, congested nose.
- Excessive tear flow.
- Abnormal sensation of the skin, itching, flaking and inflammation of the skin, blisters, acne, nail.
- Discolouration, hair loss.
- Acid heartburn.
- Dehydration.
- Hot flushes.
- Abnormally coloured urine.
- Depression.
- Chills.

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 ALSUNI

– Storage

Store below 30°C.

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton, bottle and blister foil after “EXP”. The expiry date refers to the last day of that month.

– Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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Product Description

– Dosage form

Hard capsules.

– What it looks like

ALSUNI CAPSULES 12.5 MG:

Hard capsules with dark brown opaque cap and dark brown opaque body, 13.8-14.8 mm, printed with white ink “LP” on the cap, “650” on the body, and containing yellow to orange granular powder.

ALSUNI CAPSULES 25 MG:

Hard capsules with light brown opaque cap and dark brown opaque body, 15.4-16.4 mm, printed with white ink “LP” on the cap, “651” on the body, and containing yellow to orange granular powder.

ALSUNI CAPSULES 50 MG:

Hard capsules with light brown opaque cap and light brown opaque body, 17.5-18.5 mm, printed with white ink “LP” on the cap, “653” on the body, and containing yellow to orange granular powder.

– Ingredients

Active Ingredient:

Sunitinib malate

Inactive Ingredients:

Capsule content

Povidone (K-25), Mannitol, Croscamellose sodium, Magnesium stearate.

Capsule shell

12.5 mg:

Gelatin, Red Iron Oxide (E172), Titanium Dioxide (E171), Black Iron Oxide (E172).

25 mg:

Gelatin, Titanium dioxide (E171), Red Iron Oxide (E172), Black Iron Oxide (E172), Yellow Iron Oxide (E172).

50 mg:

Gelatin, Titanium Dioxide (E171), Yellow Iron Oxide (E172), Red Iron Oxide (E172), Black Iron Oxide (E172).

Printing ink

Shellac, Propylene Glycol, Sodium Hydroxide, Povidone, Titanium Dioxide (E171).

– Details of packaging

Capsules are packed in:
White PVC/Aclar-Aluminum blister: 28 hard capsules

– MAL number

MAL22126047AZ (12.5 mg)

MAL22126048AZ (25 mg)

MAL22126049AZ (50 mg)

Manufacturer

Lotus Pharmaceutical Co., Ltd. (Nantou Plant)
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Product Registration Holder

Lotus Healthcare Malaysia Sdn Bhd
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Selangor Darul Ehsan

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