

NIBINASE 12.5, 25 and 50

Sunitinib Malate Hard Gelatin Capsule (12.5mg, 25mg and 50mg)

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What NIBINASE is used for

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

- Gastrointestinal stromal tumour (GIST), a type of cancer of the stomach and bowel, where imatinib (another anticancer medicine) no longer works or you cannot take imatinib.
- Metastatic renal cell carcinoma (MRCC), 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 NIBINASE work

NIBINASE contains the active substance sunitinib, which is a protein kinase inhibitor. It 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 NIBINASE

- When you must not use it

Do not take NIBINASE if:

- You are allergic to sunitinib or to any of the other ingredients of NIBINASE (See the end of this leaflet for a complete list of ingredients in NIBINASE).

Talk to your doctor or pharmacist before taking NIBINASE if you:

- have high blood pressure. NIBINASE can raise blood pressure. Your doctor may check your blood pressure during treatment with NIBINASE, and you may be treated with medicines to reduce the blood pressure, if needed.
- have or have had blood disease, bleeding problems, or bruising. Treatment with NIBINASE may lead to a higher risk of bleeding or lead to changes in the number of certain cells in the blood which may lead to anaemia or affect the ability of your blood to clot. If you are taking warfarin or acenocoumarole, medicines which thin the blood to prevent blood clots, there may be a greater risk of bleeding. Tell your doctor if you have any bleeding while on treatment with NIBINASE.
- have heart problems. NIBINASE can cause heart problems. Tell your doctor if you feel very tired, are short of breath, or have swollen feet and ankles.
- have abnormal heart rhythm changes. NIBINASE can cause abnormality of your heart rhythm. Your doctor may obtain electrocardiograms to evaluate for these problems during your treatment with NIBINASE. Tell your doctor if you feel dizzy, faint, or have abnormal heartbeats while taking NIBINASE.
- 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. Call your doctor immediately if you get symptoms such as chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, numbness or weakness on 1 side of your body, trouble talking, headache, or dizziness while on treatment with NIBINASE.
- have or have had an aneurysm (swelling and weakening of part of a blood vessel)
- 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. Tell your

doctor if you develop any of the following signs and symptoms: pain in the area of the stomach (upper abdomen), nausea, vomiting, and fever. These may be caused by inflammation of the pancreas or gallbladder.

- have or have had liver problems.
- have or have had kidney problems.
- are going to have surgery or if you had an operation recently.
- may be advised to have a dental check-up before you start treatment with NIBINASE
- have or have had skin and subcutaneous tissue disorders.
- have diabetes (condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This leads to hyperglycaemia (too much sugar in the blood))
- have or have had seizures

NIBINASE contains Mannitol

NIBINASE contains Mannitol as an excipient, which may have a mild laxative effect.

Children and adolescents

NIBINASE is not recommended for people aged under 18.

- Before you start to take it

Pregnancy and lactation

if you are pregnant or plan to become pregnant. You and your healthcare provider will have to decide if you should take NIBINASE while you are pregnant.

If you are breastfeeding. You should not breast-feed during treatment with NIBINASE.

- 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.

The following medicines are examples that may increase the levels of sunitinib in your blood, and hence may increase the risk for side effects:

- 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

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine. Do not start a new medicine without talking to your healthcare provider.

How to use NIBINASE

- How much to take

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- **NIBINASE** is for oral use only.
- Your healthcare provider may change your dose. Do not change your dose without talking to your healthcare provider.
- 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 MRCC: 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 take it

Use as directed by your doctor or pharmacist.

NIBINASE may be taken with or without food.

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

- How long to use it

Continue taking NIBINASE for the duration that the doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to take it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using NIBINASE

- Things you must do

Take your medicine exactly as your doctor has told you.

Stop taking NIBINASE and call your healthcare provider immediately if you have any of these signs of a serious allergic reaction:

- Swelling of your face, mouth, lips, gums, tongue, throat or neck
- Trouble breathing
- Rash, hives (raised bumps) or blisters

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

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

- Things to be careful of

Driving and using machines

Do not drive a car, work with machines, or do other dangerous activities until you know how NIBINASE affects you. Ask your healthcare provider about when it will be okay to do these activities.

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

Side Effects

Like all medicines, NIBINASE can have side effects, although not everybody gets them.

Serious side effects

If any of the following happens, tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- Fatigue, chest pain, and palpitations (cardiomyopathy)
- Lung or breathing problems (chest pain, sudden onset of shortness of breath, or coughing up blood. These may be symptoms of a condition called pulmonary embolism that occurs when blood clots travel to your lungs.)
- Kidney disorders (altered frequency or absence of urination which may be symptoms of kidney failure).
- Bleeding (serious bleeding problem during treatment with **NIBINASE**: painful, swollen stomach (abdomen); vomiting blood; black, sticky stools; bloody urine; headache or change in your mental status; coughing up of blood or bloody sputum from the lungs or airway).
- Tumour destruction leading to hole in the intestine (abdominal pain, fever, nausea, vomiting, blood in your stool, or changes in bowel habits).
- Severe reaction of the skin and/or mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme).

Other side effects

Tell your doctor if you notice any of the following:

- 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.

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- 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.
 - 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.
 - Decreased 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 discoloration, hair loss.
 - Abnormal sensations in extremities.
 - Abnormally decreased/increased sensitivity, particularly to touch.
 - Acid heartburn.
 - Dehydration.
 - Hot flushes.
 - Abnormally coloured urine.
 - Depression.
 - Chills.
 - Life-threatening infection of the soft tissue including the ano-genital region
 - damage to part of the brain caused by an interruption to its blood supply (Stroke).
 - Heart attack caused by an interrupted or decreased blood supply to the heart.
 - Changes in the electrical activity or abnormal rhythm of the heart.
 - Fluid around the heart (pericardial effusion).
 - Liver failure.
 - Pain in the stomach (abdomen) caused by inflammation of the pancreas.
 - Tumour destruction leading to hole in the intestine (perforation).
 - Inflammation (swelling and redness) of the gallbladder with or without associated gallstones.
 - Abnormal tube-like passage from one normal body cavity to another body cavity or the skin.
 - Pain in the mouth, teeth and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs and symptoms of bone damage in the jaw (osteonecrosis).
 - Overproduction of thyroid hormones which increases the amount of energy the body uses at rest.
 - Problems with wound healing after surgery.
 - Increased blood level of enzyme (creatine phosphokinase) from muscle.
 - Excessive reaction to an allergen including hay fever, skin rash, itchy skin, hives, swelling of body parts, and trouble breathing.
 - Inflammation of the colon (colitis, colitis ischaemic).
 - Tumour lysis syndrome (TLS) – TLS consists of a group of metabolic complications that can occur during treatment of cancer.
 - Abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis).
 - Abnormal changes in the brain that can cause a collection of symptoms including headache, confusion, seizures, and vision loss (reversible posterior leukoencephalopathy syndrome).
 - Painful skin ulceration (pyoderma gangrenosum).
 - Inflammation of the liver (hepatitis).
 - Inflammation of the thyroid gland.
 - Damage to the smallest blood vessels known as thrombotic microangiopathy (TMA).
 - An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections).
- Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.
- You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]
- Storage and Disposal of NIBINASE**
- Storage**
Store below 30°C
- Disposal**
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 NIBINASE looks like
- 12.5 mg**
Hard gelatin capsule with opaque reddish brown cap and opaque reddish brown body, self-lock capsule, imprinted with 'RM53' on cap and 'RM53' on body in white ink, containing Yellow to orange colored powder.
- 25 mg**
Hard gelatin capsule with opaque caramel cap and opaque reddish brown body, self-lock capsule, imprinted with 'RM54' on cap and 'RM54' on body in white ink, containing Yellow to orange colored powder.
- 50 mg**
Hard gelatin capsule with opaque caramel cap and opaque caramel body, self-lock capsule, imprinted with 'RM56' on cap and 'RM56' on body in white ink, containing Yellow to orange colored powder.
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Packing

12.5 mg

10 capsules of NIBINASE has been packed in blister and such 3 blisters of 10 capsules in a show box along with Pack insert

25 mg

7 capsules of NIBINASE has been packed in blister and such 4 blisters of 7 capsules in a show box along with Pack insert

50 mg

7 capsules of NIBINASE has been packed in blister and such 4 blisters of 7 capsules in a show box along with Pack insert.

Ingredients

Active ingredient: Sunitinib

Inactive ingredients:

Mannitol, Croscarmellose Sodium, Povidone (K 30), Magnesium Stearate, Purified Water, Iron oxide black, Iron oxide red, Iron oxide yellow, Titanium dioxide, Gelatin

- MAL no.

12.5mg: MAL23036020AZ

25mg: MAL23036021AZ

50mg: MAL23036022AZ

Manufactured by:

Sun Pharmaceutical Industries Ltd.

Survey No. 1012, Dadra-396 193

U.T of Dadra and Nagar Haveli and

Daman and Diu, India

Product Registration Holder:

RANBAXY (MALAYSIA) SDN.

BHD.

(A SUN PHARMA company)

Lot 23, Bakar Arang Industrial Estate,

08000 Sungai Petani, Kedah, Malaysia.

Date of Revision

14/01/2025

Serial number

NPRA (R2) 22/067