

NEXAVAR FILM COATED TABLETS

Sorafenib Tosylate (200mg)

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What Nexavar Tablets are used for

Nexavar is used to treat

- A type of liver cancer called hepatocellular carcinoma
- Advanced kidney cancer patients who did not get better with certain previous treatments (interferon-alpha or interleukin-2) or who cannot use those treatments (advanced renal cell carcinoma).
- Advanced or spreading thyroid cancer that failed previous therapy with radioactive iodine treatment (differentiated thyroid carcinoma).

How Nexavar Tablets work

Nexavar is a protein kinase inhibitor. It works by slowing down the growth of cancer cells and cutting off the blood supply that keeps cancer cells growing

Before you use Nexavar Tablets

- When you must not use it
Do not take this medicine if:
 - you are allergic to sorafenib tosylate or any other ingredients of this medicine (listed in Product Description)
 - you have squamous cell lung cancer and are receiving carboplatin/paclitaxel
- Before you start to use it
Check with your doctor or pharmacist before taking Nexavar Tablets if you have:
 - high blood pressure
 - heart problems (e.g. recent heart attack, chest pain)

- liver disease or severe kidney problems
- bleeding disorders
- a history of prolonged QT interval (irregular heart rhythm)
- low levels of calcium or thyroid problems
- very large tumours or certain blood/urine changes that increase risk of tumour lysis syndrome
- are scheduled for major surgery – treatment may need to be paused before and after

Pregnancy and lactation

Do not take Nexavar if you are pregnant because it can seriously harm your unborn baby, including causing birth defects or even loss of the pregnancy. If you could become pregnant, you must use effective birth control while taking Nexavar and for at least 2 weeks after your last dose. Tell your doctor immediately if you become pregnant during treatment.

Do not breastfeed while taking Nexavar. The medicine may pass into breast milk and harm your baby. Talk to your doctor about safe feeding options for your child while you are on this treatment.

Fertility

Nexavar may affect your ability to have children (both men and women). In some cases, these effects could be permanent. If you plan to have children in the future, discuss fertility preservation options (like sperm or egg storage) with your doctor before starting treatment.

- Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or even over-the-counter medicines, such as vitamins or dietary supplements. Some medicines may affect the way Nexavar works or Nexavar may affect how other medicines work and cause serious side effects. Tell your doctor if you

are taking any of the following medicines:

- Rifampicin (for infections such as tuberculosis)
- Oral neomycin or other antibiotics
- St John's wort, an herbal treatment for depression
- Phenytoin carbamazepine or phenobarbital, treatments for epilepsy and other conditions
- Dexamethasone, a corticosteroid used for inflammation and other conditions
- Warfarin, or other blood thinners
- Doxorubicin, capecitabine, docetaxel, paclitaxel and irinotecan, which are cancer medicines

How to use Nexavar Tablets

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

- How much to use

The usual dose is 2 tablets to be taken twice daily.

- When to use it

Take 2 tablets twice a day or every 12 hours (for example, morning and evening).

Swallow Nexavar tablets with a glass of water, either with or without food.

Do not take this medicine with high fat meals, as this may make Nexavar Tablets less effective. If you intend to have a high fat meal, take the tablets at least 1 hour before or 2 hours after the meal

It is important to take Nexavar at about the same times each day, to keep a steady level in your body.

- How long to use it

Take this medicine for the duration that your doctor recommends.

- If you forget to use 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 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

Taking too much Nexavar can cause more severe side effects, such as very bad diarrhoea, skin problems (rash, redness and blistering on hands and feet),

While you are using Nexavar Tablets

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Nexavar Tablets.

Tell your doctor immediately if you become pregnant while using this medication.

Take Nexavar Tablets only with a doctor's prescription.

- Things you must not do

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

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

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

- Things to be careful of

Nexavar can cause redness, pain, swelling, or blisters, especially on your hands and feet. Check your skin often and tell your doctor if you notice these changes so they can be treated early.

This medicine can raise your blood pressure. Your doctor will check it regularly, and you may need medicine to keep it under control.

Let your doctor know right away if you have nosebleeds, unusual bruising, blood in your stool or urine, or if you cough or vomit blood or if you notice yellow skin or eyes, dark urine, or if you feel unusually tired.

If you have thyroid cancer, Nexavar may affect your thyroid hormone or calcium levels. Your doctor will do blood tests to monitor these.

Nexavar may possibly cause a hole (perforation) in your stomach or intestines. Call your doctor right away if you have sudden, severe stomach pain.

Side effects

Like all medicines, Nexavar Tablets can cause side effects, although not everybody gets them. The possible side effects are:

Very common

- infection
- low lymphocytes (a type of white blood cell) (lymphopenia)
- loss of appetite (anorexia)
- low phosphorus level in the blood (hypophosphataemia)
- bleeding, including bleeding in the brain, gut or lungs (hemorrhage)
- high blood pressure (hypertension)
- diarrhoea (loose stools)
- feeling sick (nausea)
- throwing up (vomiting)
- constipation
- dry skin
- rash
- hair loss (*alopecia*)
- redness, pain, sweating, or thickening of the skin on the hands and/or feet (hand-foot skin reaction)
- itchy skin (pruritus)
- redness of skin (erythema)
- joint pain (arthralgia)
- feeling tired (fatigue)
- general pain (including mouth pain, abdominal pain, bone pain, tumor pain, and headache)
- fever
- weight loss
- high amylase or lipase (enzymes) in blood tests

Common

- inflammation of hair follicles (folliculitis)
- low white blood cells (leucopenia, neutropenia)
- low red blood cells (anaemia)
- low platelets (thrombocytopenia)
- underactive thyroid gland (hypothyroidism)
- low calcium (hypocalcaemia)
- low potassium (hypokalaemia)
- low sodium (hyponatraemia)
- depression
- tingling, numbness, or burning feeling in hands/feet (peripheral sensory neuropathy)
- changes in taste (dysgeusia)
- ringing in the ears (tinnitus)
- heart problems, congestive heart failure, heart attack (myocardial infarction), chest pain (ischaemia)
- flushing (red, warm skin)
- runny nose (rhinorrhea)
- hoarse voice (dysphonia)
- sore or dry mouth, inflamed tongue (stomatitis, glossodynia)
- indigestion (dyspepsia)
- difficulty swallowing (dysphagia)
- heartburn (gastrooesophageal reflux disease)
- skin cancer (keratoacanthomas or squamous cell carcinoma)
- inflamed, peeling, or scaly skin (dermatitis, skin desquamation)
- acne
- thickened skin (hyperkeratosis)
- muscle pain (myalgia)
- muscle spasms
- kidney failure (renal failure)
- protein in urine (proteinuria)
- erection problems (erectile dysfunction)
- feeling weak (asthenia)
- flu-like illness
- mucosal inflammation
- temporary rise in liver enzymes (transaminases)

Uncommon

- severe allergic reaction (anaphylaxis)
- hypersensitivity reactions (including skin reactions and hives)
- overactive thyroid (hyperthyroidism)
- dehydration
- posterior reversible encephalopathy syndrome

(reversible brain swelling causing headache, confusion, seizures, vision changes) - severely elevated blood pressure (hypertensive crisis) - lung problems, including scarring or inflammation (interstitial lung disease-like events) - inflammation of the pancreas (pancreatitis) - inflammation of the stomach lining (gastritis) - holes in the stomach or intestines (gastrointestinal perforation) - jaundice (yellowing of skin/eyes) - gallbladder inflammation (cholecystitis) - bile duct inflammation (cholangitis) - eczema - severe peeling or blistering skin reactions (erythema multiforme) - non-cancerous growth of one or both breasts in men and women (gynaecomastia) - temporary rise in blood alkaline phosphatase - abnormal blood clotting time (INR abnormal/prothrombin level abnormal)	Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].	Date of revision 19/09/2025
<i>Rare</i> - abnormal heart rhythm (QT prolongation) - liver inflammation (drug-induced hepatitis) - kidney disease with protein loss (nephrotic syndrome) <i>Unknown frequency</i> - radiation recall reaction (rash at previous radiotherapy site) - Stevens–Johnson syndrome - blood vessel inflammation in skin (leukocytoclastic vasculitis) - toxic epidermal necrolysis (life-threatening skin reaction) - muscle breakdown that can damage kidneys (rhabdomyolysis)	Storage and Disposal of Nexavar Tablets - <u>Storage</u> Keep out of the reach and sight of children. Store below 30 °C. - <u>Disposal</u> 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 - <u>What it looks like</u> Red round, faceted, biconvex film coated tablet. One side has a Bayer cross and the other side “200”. - <u>Ingredients</u> - Active ingredient - Sorafenib tosylate - Inactive ingredients - Tablet core: croscarmellose sodium, microcrystalline cellulose, hydroxypropylmethyl cellulose, sodium lauryl sulfate, magnesium stearate - Film coat: hypromellose 5 cps, macrogol, titanium dioxide E171, ferric oxide E172 red - <u>MAL number:</u> MAL20071668ACZ Manufacturer Patheon France S.A.S 40, Boulevard de Champaret 38300 Bourgoin-Jallieu France	Serial Number NPRA(R4/1)110825/00062
Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. 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 →	Product Registration Holder Bayer Co (Malaysia) Sdn Bhd 25-03 & 25-04, Level 25, IMAZIUM, No 8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor Darul Ehsan.	