

NEXAVAR®

(NEX-a-var)

sorafenib tosylate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Nexavar.

This leaflet does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Nexavar against the benefits they expect it will have for you.

Nexavar is a prescription medicine. It should only be used under medical supervision.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT NEXAVAR IS USED FOR

Nexavar is used to treat advanced liver cancer (hepatocellular carcinoma), advanced kidney cancer (renal cell carcinoma), or thyroid cancer (differentiated thyroid carcinoma).

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

Nexavar should be prescribed and managed only by healthcare professionals specialising in treating your type of cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE NEXAVAR

When you must not take it

Do not take Nexavar if you have an allergy to:

- sorafenib tosylate, the active ingredient in Nexavar
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or breast-feeding.

Women should avoid becoming pregnant while undergoing treatment with Nexavar.

You should speak to your doctor right away if you think that you are pregnant because Nexavar may harm the foetus. Both men and women should use effective birth control measures.

Nexavar is not recommended for use while breast-feeding because it could harm the baby.

Do not give Nexavar to children or growing adolescents.

Tell your doctor if you:

- **Experience skin problems.** Nexavar can cause rashes and skin reactions, especially on hands and feet. These can usually be treated by your doctor. If not, your Nexavar treatment may be interrupted or stopped altogether.

- **Have high blood pressure.**
Nexavar can raise blood pressure, and your doctor will usually monitor your blood pressure and may give you medicine to treat your high blood pressure.
- **Have any bleeding problems, or are taking warfarin.**
Treatment with Nexavar may lead to a higher risk of bleeding. If you are taking warfarin, which thins the blood to prevent blood clots, there may be a greater risk of bleeding.
- **Are going to have surgery, or you have had an operation recently.**
Nexavar might affect the way your wounds heal. You will usually be taken off Nexavar if you are having an operation. Your doctor will decide when to start with Nexavar again.
- **Suffer from chest pain (angina) or have suffered a heart attack (myocardial infarction) recently.**
Your doctor may decide to interrupt treatment or stop it altogether.
- **Have an abnormality of your heart trace known as prolonged QT interval.**
Nexavar may affect your heart rhythm.
- **Have severe hepatic impairment (liver failure).**
You may experience more severe side effects when taking this medicine.
- **Are taking irinotecan (Camptosar), capecitabine (Xeloda) or docetaxel (Taxotere), which are other drugs used in the treatment of cancer, or other related drugs.**
You may experience more side effects when taking combination therapy.
- **If you have thyroid cancer, your doctor will monitor blood calcium and thyroid hormone levels.**

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Nexavar.

You may need extra treatment, or your doctor may decide to change your dose of Nexavar, or stop treatment altogether.

Taking other medicines

Whilst being treated with Nexavar, you must seek your doctor's advice before taking any other medication, whether provided on a prescription or bought from a pharmacy, supermarket or health food shop including any over-the-counter drugs, vitamins, or herbal medicines.

Some medication may be affected by Nexavar or vice versa. These medicines are:

- Rifampicin and neomycin, which are antibiotics
- St John's Wort, a herbal treatment for depression
- Phenytoin, carbamazepine or phenobarbital, treatments for epilepsy and other conditions
- Dexamethasone, a corticosteroid used for various conditions.
- Warfarin, an anticoagulant used to prevent blood clots
- Doxorubicin, capecitabine, paclitaxel, carboplatin, irinotecan or docetaxel which are other cancer treatments.

You may need to use different amounts of your medicine or a different medicine. Your doctor will be able to advise you. Your doctor and pharmacist will have a complete list of medicines to be careful of and to avoid while taking Nexavar.

HOW TO TAKE NEXAVAR

Always take Nexavar exactly as your doctor has told you to.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacy label, ask your doctor or pharmacist for help.

How much to take

The usual dose of Nexavar is two 200 mg tablets twice a day.

This is equivalent to 800 mg total daily dose.

Your doctor may put you on a lower dose or stop Nexavar treatment if you get severe side effects - in particular high blood pressure, bleeding or skin reactions.

If you are worried, talk to your doctor or pharmacist.

How to take it

Swallow the tablets whole with a full glass of water.

Take Nexavar either without food or with a low fat or moderate fat meal. Do not take this medicine with high fat meals, as this may make your Nexavar less effective.

When to take it

Take your Nexavar tablets at the same time each day.

Taking it at the same time each day (usually morning and evening) will have the best effect. It will also help you remember when to take it.

If you forget to take it

If you miss a dose of Nexavar, do not take the missed dose and do not double the next one. Instead, continue your regular dosing schedule and check with your doctor.

How long to take it

Your doctor will continue to treat you with Nexavar as long as you are receiving benefit from therapy. Your doctor might interrupt your Nexavar therapy and/or change the number of tablets you take every day depending on how you are tolerating it.

If you take too much (overdose)

There is no information on symptoms of Nexavar overdose.

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26 or New Zealand: 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Nexavar. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING NEXAVAR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Nexavar.

Take Nexavar exactly as told by your doctor.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Nexavar.

Tell your doctor if you are taking medicine to thin your blood such as warfarin.

Tell your doctor if you need to have a surgical or dental procedure.

It is not known whether Nexavar will affect your ability to drive or to operate machinery, but if you feel light-headed stop the activity and consult your doctor.

Things you must not do

Do not take Nexavar to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Nexavar.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Diarrhoea
- Feeling and/or being sick (nausea and/or vomiting)
- Feeling weak or tired
- Fever, flu-like illness
- Constipation
- Dry mouth, difficulty swallowing, hoarseness
- Indigestion
- Loss of appetite, weight loss
- Ringing in the ear (tinnitus)
- Pain (including mouth pain, abdominal pain, headache, bone pain, joint pain and muscle pain)
- Hair thinning or patchy hair loss
- Flushing

- Redness, pain, swelling or blistering on the palms or soles of your feet (called hand foot skin reaction)
- Disturbed sensations in fingers and toes, including tingling or numbness
- Muscle cramps, weakness and/or spasms in your legs and arms or heart palpitations which can be from low levels of calcium or potassium in your blood
- Frothy urine, swelling in abdomen, face, feet or hands which can be from abnormally high levels of protein in urine
- Inflamed, dry or scaly skin that sheds
- Acne
- Itching or rash
- Bleeding (haemorrhage)
- Depression
- Erection problems (impotence)
- High blood pressure, or increases in blood pressure. You may not experience any specific symptoms but your doctor will check you regularly for this side effect and may start or change your blood pressure treatment.
- Passing little or no urine, drowsiness, nausea, vomiting, breathlessness. These symptoms may be associated with a decrease in the function of your kidneys.
- Infections
- Heartburn
- Skin cancer
- Distortion of the sense of taste
- Runny nose

These are the more common side effects, other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- Chest pain which may spread to the neck and shoulders, changes in the way your heart beats (for example, if you notice it beating faster), abnormal heart rhythm
- Severe headache, confusion, seizures, visual loss
- Vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- Shortness of breath, difficulty breathing, swelling of the feet or legs due to fluid build-up
- Severe abdominal pain intensified by movement, nausea, vomiting, fever and/or chills
- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, mouth, tongue, throat or other parts of the body, shortness of breath, wheezing or trouble breathing, difficulty in swallowing
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (a rare skin condition known as Stevens-Johnson syndrome)
- sun-burn like rash that may occur on skin that has been previously exposed to radiotherapy and can be severe (a condition known as radiation recall dermatitis)
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (these symptoms may be associated with liver disease)
- inflammation of small blood vessels (a condition known as leukocytoclastic vasculitis)
- temporary paralysis or weakness of muscles (a condition known as rhabdomyolysis)
- swelling of face, legs, abdomen and body from damage of the kidney causing them to leak large amounts of protein (a condition known as nephrotic syndrome)

These may be more serious side effects of Nexavar. You may need urgent medical attention. Serious side effects are rare and uncommon.

AFTER TAKING NEXAVAR

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the box or blister pack they may not keep well.

Store the tablets in a cool dry place where the temperature stays below 25°C.

Do not store Nexavar or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep all medicines out of reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

Nexavar is packed in blister packs of 60 tablets. They are red, round film-coated tablets marked with "200" on one side and the "BAYER" cross on the other side.

Ingredients

Active ingredient:

- Nexavar - 200 mg sorafenib as sorafenib tosylate

Inactive ingredients:

- croscarmellose sodium
- microcrystalline cellulose
- hypromellose
- sodium lauryl sulphate
- magnesium stearate
- macrogol
- titanium dioxide
- iron oxide red

Supplier

Made in Germany for:
Bayer Australia Ltd
 ABN 22 000 138 714
 875 Pacific Highway
 Pymble, NSW 2073

Bayer New Zealand Limited
 3 Argus Place, Hillcrest
 North Shore, Auckland 0627

Australian Registration Number

- Nexavar 200 mg - AUST R 123158

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April 2014

See TGA website

(www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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