

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using NEXAVAR?

NEXAVAR contains the active ingredient sorafenib tosilate. NEXAVAR is used to treat advanced liver cancer (hepatocellular carcinoma), advanced kidney cancer (renal cell carcinoma), or thyroid cancer (differentiated thyroid carcinoma).

For more information, see Section [1. Why am I using NEXAVAR?](#) in the full CMI.

### 2. What should I know before I take NEXAVAR?

Do not use if you have ever had an allergic reaction to NEXAVAR or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

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

For more information, see Section [2. What should I know before I take NEXAVAR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NEXAVAR and affect how it works. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take NEXAVAR?

- **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.
- 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.

More instructions can be found in Section [4. How do I take NEXAVAR?](#) in the full CMI.

### 5. What should I know while taking NEXAVAR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using NEXAVAR.</li><li>• Tell your doctor if you are taking medicine to thin your blood such as warfarin.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Follow the instruction in the carton on how to take care of your medicine properly.</li><li>• Store it in a cool dry place away from moisture, heat or sunlight</li></ul>

For more information, see Section [5. What should I know while taking NEXAVAR?](#) in the full CMI.

### 6. Are there any side effects?

Like all medicines, NEXAVAR can cause side effects, although not everybody gets them. The most common side effects are diarrhea, feeling weak or tired, hair thinning or patchy hair loss, infection, rash, hand-foot skin reaction. Serious side effects include chest pain with abnormal heart rhythm, severe headaches and seizure, vomiting blood, severe abdominal pain, nausea, blisters, bleeding, and high blood pressure. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# NEXAVAR<sup>®</sup> (NEX-a-var)

Active ingredient(s): *sorafenib tosilate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NEXAVAR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NEXAVAR.**

Where to find information in this leaflet:

- [1. Why am I using NEXAVAR?](#)
- [2. What should I know before I take NEXAVAR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take NEXAVAR?](#)
- [5. What should I know while taking NEXAVAR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using NEXAVAR?

NEXAVAR contains the active ingredient **sorafenib tosilate**. 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 is used to **treat advanced liver cancer (hepatocellular carcinoma), advanced kidney cancer (renal cell carcinoma), or thyroid cancer (differentiated thyroid carcinoma).**

### 2. What should I know before I take NEXAVAR?

#### Warnings

**Do not take NEXAVAR if:**

- you are allergic to sorafenib tosilate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

**Check with 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.
- Have a history of aneurysm.** Your doctor may discuss with you the risk of taking NEXAVAR
- 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.
- Have thyroid cancer, your doctor will monitor blood calcium and thyroid hormone levels.**
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

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.

Check with your doctor if you intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

NEXAVAR is not recommended for use while breastfeeding because it could harm the baby.

## Children and adolescents

- The safety and effectiveness of NEXAVAR in paediatric patients has not been established. Do not give NEXAVAR to children or growing adolescents.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NEXAVAR.**

### 4. How do I take NEXAVAR?

#### 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.
- Follow the instructions provided and use NEXAVAR until your doctor tells you to stop.
- 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.

#### When to take NEXAVAR

- NEXAVAR should be used 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.

#### How to take NEXAVAR

- 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.

#### If you forget to take NEXAVAR

NEXAVAR should be taken regularly at the same time each day. If you miss your dose at the usual time, take your missed dose as soon as you remember prior to the next scheduled dose.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to and check with your doctor.**

**Do not take a double dose to make up for the dose you missed.**

#### If you take too much NEXAVAR

If you think that you have taken too much NEXAVAR, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26 for Australia**), or
- by calling 0800 POISON (**0800 764 766 for New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while taking NEXAVAR?

#### Things you should do

- Tell your doctor if you are taking medicine to thin your blood such as warfarin.
- Remind any doctor, dentist or pharmacist you visit that you are using NEXAVAR.

#### Things you should not do

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

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how NEXAVAR affects you.**

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.

#### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Diarrhoea</li> <li>• Feeling and/or being sick (nausea and/or vomiting)</li> <li>• Feeling weak or tired</li> <li>• Fever, flu-like illness</li> <li>• Constipation</li> <li>• Dry mouth, difficulty swallowing, hoarseness</li> <li>• Indigestion</li> <li>• Loss of appetite, weight loss</li> <li>• Ringing in the ear (tinnitus)</li> <li>• Pain (including mouth pain, abdominal pain, headache, bone pain, joint pain and muscle pain)</li> <li>• Hair thinning or patchy hair loss</li> <li>• Flushing</li> <li>• Redness, pain, swelling or blistering on the palms or soles of your feet (called hand foot skin reaction)</li> <li>• Disturbed sensations in fingers and toes, including tingling or numbness</li> <li>• 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</li> <li>• Frothy urine, swelling in abdomen, face, feet or hands which can be from abnormally high levels of protein in urine</li> <li>• Inflamed, dry or scaly skin that sheds</li> <li>• Acne</li> <li>• Itching or rash</li> <li>• Bleeding (haemorrhage)</li> <li>• Depression</li> <li>• Erection problems (impotence)</li> <li>• 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.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Common side effects	What to do
<ul style="list-style-type: none"> <li>• Passing little or no urine, drowsiness, nausea, vomiting, breathlessness. These symptoms may be associated with a decrease in the function of your kidneys.</li> <li>• Infection</li> <li>• Heartburn</li> <li>• Skin cancer</li> <li>• Distortion of the sense of taste</li> <li>• Runny nose</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• 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</li> <li>• Severe headache, confusion, seizures, visual loss</li> <li>• Vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea</li> <li>• Shortness of breath, difficulty breathing, swelling of the feet or legs due to fluid build-up</li> <li>• Severe abdominal pain intensified by movement, nausea, vomiting, fever and/or chills</li> <li>• 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</li> <li>• severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (a rare skin condition known as Stevens-Johnson syndrome)</li> <li>• 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)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness (a condition known as tumour lysis syndrome). This condition can lead to changes in kidney function and acute renal failure</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) (Australia) or at <https://nzphvc.otago.ac.nz/reporting/> (New Zealand). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What NEXAVAR contains

<b>Active ingredient (main ingredient)</b>	sorafenib tosilate
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>croscarmellose sodium</li> <li>microcrystalline cellulose</li> <li>Hypromellose</li> <li>sodium lauryl sulphate</li> <li>magnesium stearate</li> <li>macrogol</li> <li>titanium dioxide</li> <li>iron oxide red</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What NEXAVAR looks like

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

### Registration number

- AUST R 123158 (Australia)
- TT50-7632 (New Zealand)

### Who distributes NEXAVAR

Bayer Australia Ltd  
ABN 22 000 138 714  
875 Pacific Highway  
Pymble, NSW 2073

Bayer New Zealand Limited  
PO Box 2825  
Shortland Street,  
Auckland 1140

This leaflet was prepared on 22 November 2023.

See TGA website

([www.ebs.tga.gov.au](http://www.ebs.tga.gov.au)) for latest Australian Consumer Medicine Information.

See MEDSAFE website

([www.medsafe.govt.nz](http://www.medsafe.govt.nz)) for latest New Zealand Consumer Medicine Information.

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