



CONDITIONAL APPROVAL OF NEXAVAR[®]

FACT SHEET

What is NEXAVAR[®]?

NEXAVAR[®] (sorafenib tablets) is an oral anticancer agent known as a multikinase inhibitor supplied as a tablet containing 200 mg of sorafenib as sorafenib tosylate.

Health Canada has approved NEXAVAR with conditions, under the Notice of Compliance with Conditions (NOC/c) policy. This authorisation reflects the promising nature of the clinical evidence which must be confirmed with further studies. Products approved under Health Canada's NOC/c policy have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment for the approved use. This approval was based on increased progression-free survival (PFS) over placebo (no active therapy). Evidence of prolonged survival has not yet been established.

What is NEXAVAR used for?

NEXAVAR is used for the treatment of kidney cancer (locally advanced / metastatic renal cell [clear cell] carcinoma) in patients who failed prior cytokine therapy or are considered unsuitable for such therapy.

What is renal cell carcinoma?

Renal cell (clear cell) carcinoma (RCC) is the most common type of kidney cancer in adults, causing about 85 per cent of all kidney cancers. Almost one-third of people with RCC have locally advanced / metastatic disease at the time of diagnosis.

How does NEXAVAR work?

NEXAVAR is a multikinase inhibitor, which means that the drug selectively targets kinases involved in both the growth of tumour cells and in the growth of tumour blood vessels. NEXAVAR slows down the rate of tumour growth by cutting off the blood supply that keeps tumours growing.

What are the advantages of NEXAVAR over currently available treatments?

Treatment options for patients with locally advanced / metastatic RCC are limited. The available treatments include cytokines. Patients with locally advanced / metastatic RCC are often not suitable for cytokine therapy. For many patients, locally advanced / metastatic RCC remains a serious, life-threatening condition with few treatment options. NEXAVAR provides a new option for patients who are unsuitable for cytokine therapy.

What do patients need to know about using NEXAVAR?

NEXAVAR should be prescribed and managed only by an oncologist or healthcare professional specializing in treating kidney cancer.

Possible serious side effects include high blood pressure, bleeding and heart attack. NEXAVAR has not been studied in patients who have severe kidney problems (in addition to kidney cancer) or severe liver problems.

BEFORE you use NEXAVAR, talk to your doctor or pharmacist if:

- You have high blood pressure.
- You have had a history of heart problems.
- You have bleeding problems, or are taking warfarin.
- You are going to have surgery or a dental procedure, or if you had an operation recently.
- You have abnormal kidney function (in addition to kidney cancer) or liver problems.
- You are pregnant, may be pregnant or are thinking about becoming pregnant. NEXAVAR may reduce fertility in both men and women. NEXAVAR can harm an unborn baby. You must use effective contraception while you take NEXAVAR.
- You are breast-feeding.

Can Nexavar be taken with other drugs?

Some drugs are broken down in the liver by the same route as NEXAVAR, so patients must inform their physician if they are taking other drugs.

What are the most common side effects of NEXAVAR?

Like all medicines, NEXAVAR can have side effects. The side effects of treatment with Nexavar during clinical trials were mostly mild to moderate in severity. In the pivotal Phase III trial, the most commonly reported side effects were:

- diarrhea
- itching or rash
- feeling weak or tired
- flushed or painful palms or soles (hand-foot syndrome)
- hair loss
- feeling sick (*nausea*)
- inflamed, dry or scaly skin that sheds
- high blood pressure, or increases in blood pressure
- throwing up (*vomiting*)
- loss of appetite
- weight loss
- constipation
- bleeding (*hemorrhage*) including bleeds from the mouth, nose, stomach or gut, rectum or back passage, lungs or windpipe, bleeding nail beds and blood blisters
- cough and breathlessness
- numbness, tingling or pain in your hands and feet

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- pain (including mouth pain, abdominal pain, headache, bone pain, joint pain and muscle pain)

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If any of the side effects happen to you, ask your doctor for advice. Many of them can be treated.

Who should not be treated with NEXAVAR?

- patients allergic (hypersensitive) to sorafenib or any of the other ingredients of NEXAVAR
- children under 18 years of age
- women who may be pregnant or are thinking about becoming pregnant
- nursing women

How is NEXAVAR taken?

The usual dose of NEXAVAR is two 200 mg tablets taken twice a day. Swallow the NEXAVAR tablets with water without food.

Always take NEXAVAR exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure. It is important to take NEXAVAR at about the same times each day.

What if you forget to take a dose?

If you have missed a dose, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose and carry on as normal. Do not take a double dose to make up for forgotten individual doses.

What should you do in case of an overdose?

Tell your doctor or health care provider immediately if you (or anyone else) have taken more than your prescribed dose.

What else should patients know about taking NEXAVAR?

Store at room temperature between 15–30°C in a dry place. This medicine does not need any other special storage conditions.

Where can I learn more about NEXAVAR?

For medical enquiries, contact Bayer Inc. at 1-800-265-7382.

Or visit Bayer's website at: www.bayerhealth.ca

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