

PART III: CONSUMER INFORMATION

PrNEXAVAR®
sorafenib tablets

This leaflet is Part 3 of a three-part "Product Monograph" published when NEXAVAR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NEXAVAR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

NEXAVAR is used to treat liver cancer (*hepatocellular carcinoma*) which cannot be removed by surgery.

NEXAVAR is also used to treat kidney cancer (*locally advanced / metastatic renal cell (clear cell) carcinoma*) in adults who failed or are intolerant to prior systemic therapy. It is not known whether NEXAVAR prolongs overall survival or improves the quality of life of patients with kidney cancer.

What it does:

NEXAVAR is a *multikinase inhibitor*. As a multikinase inhibitor, it works by blocking some specific enzymes which are involved in the growth and spread of cancer cells and in the development of new blood vessels that supply the tumours.

When it should not be used:

Do not take NEXAVAR if you are allergic (hypersensitive) to sorafenib tosylate or any of the other ingredients of NEXAVAR.

What the medicinal ingredient is:

Sorafenib tosylate

What the nonmedicinal ingredients are:

The other tablet ingredients are: croscarmellose sodium, microcrystalline cellulose, hydroxypropylmethyl cellulose, sodium lauryl sulfate, magnesium stearate.

The tablet coating contains: hydroxypropylmethyl cellulose, macrogol, titanium dioxide, ferric oxide red.

What dosage forms it comes in:

NEXAVAR is supplied as a tablet containing 200 mg of sorafenib. These tablets are red, round and film-coated, with the Bayer cross on one side and "200" on the other side. They come in bottles containing 120 tablets.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

This drug should be prescribed and managed only by a doctor experienced in anticancer drugs.

- NEXAVAR has not been studied in patients who have severe liver problems.
- Of note, possible serious side-effects with NEXAVAR include high blood pressure, bleeding, heart attack and gastrointestinal (bowel) perforation.

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

- You have high blood pressure. NEXAVAR can raise blood pressure. Your doctor will instruct you to monitor your blood pressure and may give you medicine to treat your high blood pressure.
- You have 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.
- You are going to have surgery, or a dental procedure, or if you 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.
- You have kidney or liver problems (in addition to cancer)
- 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 breastfeeding. You should not breastfeed during NEXAVAR treatment because it could harm the baby.
- You have had a history of heart problems.

NEXAVAR should not be given to children.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with NEXAVAR include:

- Rifampin (ROFACT®, RIFADIN®), an antibiotic

- St John's Wort, a herbal treatment for depression
- Phenytoin (DILANTIN[®]), carbamazepine (TEGRETOL[®]), dexamethasone (MAXIDEX[®]) or phenobarbital (BELLERGA SPACETABS[®]), treatments for epilepsy and other conditions
- Warfarin (COUMADIN[®]), an anticoagulant used to prevent blood clots
- Doxorubicin (ADRIAMYCIN PFS[®], CAELYX[®], MYOCET[®]), docetaxel (TAXOTERE[®]), and irinotecan (CAMPTOSAR[®]), which are other cancer treatments
- Neomycin, an antibiotic

Tell your doctor or pharmacist if you are taking these or any other medicines even those not prescribed (including any over-the-counter drugs, vitamins, or herbal medicines).

See also ABOUT THIS MEDICATION: When it should not be used, and SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

PROPER USE OF THIS MEDICATION

Usual dose

The usual dose of NEXAVAR in adults is two 200 mg tablets, twice daily.

How to take NEXAVAR

Swallow NEXAVAR tablets with a glass of water, without food or with a low-fat to moderate-fat meal. 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.

Overdose

Tell your doctor immediately or contact the nearest poison control center or the emergency room of the nearest hospital if you (or anyone else) have taken more than your prescribed dose.

Missed Dose

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

How long will I take NEXAVAR?

Your doctor will continue to treat you with NEXAVAR as long as you are thought to be benefiting from therapy.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

NEXAVAR can have side effects, like all medicines, but not everybody gets them. For further information about any of these effects, ask a doctor or pharmacist.

If you experience any symptom that bothers you or does not go away, or severe side effects such as high blood pressure, bleeding or skin reactions, contact your doctor or seek medical attention as soon as possible.

The following side effects have been observed during clinical trials involving men and women taking NEXAVAR:

Very common side effects

(may affect 10 or more in every 100 people)

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

Common side effects

(may affect 1 to 9 in every 100 people)

- flushing
- acne
- flu-like illness
- fever
- indigestion or heartburn
- difficulty swallowing
- depression
- erection problems (*impotence*)
- hoarseness
- heart attack (severe chest pain, shortness of breath, cold sweat, etc)
- kidney failure
- infection/inflammation of the gallbladder and/or bile ducts

The following side effects have been observed outside of clinical trials:

- heart failure (weakening of the heart muscle)
- decreased blood flow to the heart and heart attack
- severe skin condition with rash, skin peeling and sores of the mucous membranes
- increase in thyroid activity (may lead to nervousness, fast heart beat, anxiety, sweating and weight loss)
- allergic reaction due to increased sensitivity to NEXAVAR, which may lead to flushing, rashes, hives, itching, swelling, breathing difficulty, dizziness and chest discomfort
- swelling of the tissues underneath the skin (welts) due to an allergic reaction, often affecting the facial region
- inflammation of the lung which may lead to breathing problems

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect	Talk with your doctor or pharmacist	
	Only if severe	In all cases
Very Common/ Common		
Rash including hives, redness or itching of your skin	✓	
Redness, pain, swelling or blistering on the palms or soles of your feet (called hand-foot skin reaction)		✓
Diarrhea (frequent and/or loose bowel movements)	✓	
Feeling sick - Nausea and/or vomiting	✓	
Bleeding from the mouth, nose, blood in stool, coughing up blood, bleeding nail beds		✓
Feeling weak or tired	✓	
Numbness, tingling or pain in your hands and feet	✓	
Fever		✓
Joint or muscle pain	✓	
Inflamed or dry mouth, tongue pain	✓	
Weight loss	✓	
Difficulty swallowing	✓	
Heartburn	✓	
Inflamed, dry or scaly skin that sheds	✓	
Increase in blood pressure		✓
Breathlessness		✓
Uncommon		
Stomach pain	✓	
Yellowing of skin or eyes		✓
Dehydration		✓
Persistent runny nose	✓	
Heart Attack		✓
Eczema	✓	
Multiple skin eruptions		✓

This is not a complete list of side effects. For any unexpected effects while taking NEXAVAR, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature between 15°C–30°C in a dry place.

Do not use the tablets after the expiry date. This is shown on the bottle.

Keep out of the reach and sight of children and pets.

This medicine does not need any other special storage conditions.

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.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online: www.healthcanada.gc.ca/medeffect

Call toll-free at: 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, please contact your health care professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting the sponsor, Bayer Inc., at: 1-800-265-7382.

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