

## 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 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.

NEXAVAR is also used to treat thyroid cancer in patients who are no longer responding to radioactive iodine.

#### **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.

Possible serious side-effects with NEXAVAR include:

- high blood pressure
- bleeding
- heart attack
- gastrointestinal (bowel) perforation
- liver injury

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). If you have severe liver problems, you may experience more severe side effects when taking NEXAVAR.

- 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.
- You have QT/QTc prolongation or a family history of QT/QTc prolongation.
- You have a personal history of fainting spells.
- You have a family history of sudden cardiac death at <50 years.
- You have electrolyte disturbances (eg, low blood potassium or magnesium levels) or conditions that could lead to electrolyte disturbances (eg, vomiting, diarrhea, dehydration).
- You have an eating disorder or are following a strict diet.
- You have diabetes.
- You have thyroid cancer, as your doctor will monitor blood calcium and thyroid hormone levels.

NEXAVAR has an effect on the electrical activity of the heart known as QT/QTc prolongation. This effect can be measured as a change in the electrocardiogram (ECG). In very rare cases, drugs with this effect on the ECG can lead to disturbances in heart rhythm (arrhythmias/ dysrhythmias) that could result in dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting or death. These heart rhythm disturbances are more likely in patients with risk factors, such as heart disease, or in the presence of certain interacting drugs. In general, females and people more than 65 years in age are at higher risk. It is important to follow the instructions of your doctor with regard to dosing or any special tests. If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, you should seek immediate medical attention.

Electrocardiograms (ECGs) and blood tests may be required periodically to monitor the risk of potentially serious side effects during treatment with NEXAVAR.

Your thyroid gland may become underactive or overactive while you take NEXAVAR. Your doctor will check your thyroid with blood tests.

NEXAVAR should not be given to children.

## INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with NEXAVAR include:

- Rifampin (ROFACT<sup>®</sup>, RIFADIN<sup>®</sup>), an antibiotic
- St John's Wort, a herbal treatment for depression
- Phenytoin (DILANTIN<sup>®</sup>), carbamazepine (TEGRETOL<sup>®</sup>), dexamethasone (MAXIDEX<sup>®</sup>) or phenobarbital (BELLERGA SPACETABS<sup>®</sup>), treatments for epilepsy and other conditions
- Warfarin (COUMADIN<sup>®</sup>), an anticoagulant used to prevent blood clots
- Doxorubicin (ADRIAMYCIN PFS<sup>®</sup>, CAELYX<sup>®</sup>, MYOCET<sup>®</sup>), docetaxel (TAXOTERE<sup>®</sup>), and irinotecan (CAMPTOSAR<sup>®</sup>), paclitaxel (TAXOL<sup>®</sup>), carboplatin, and capecitabine (XELODA<sup>®</sup>), which are other cancer treatments
- Neomycin, an antibiotic
- Drugs to treat heart rhythm disturbances
- Antidepressants
- Antipsychotics
- Painkillers
- Antibiotics
- Drugs to treat nausea and vomiting
- Other cancer drugs
- Diuretics (water pills)

This list includes some, but not all, of the drugs that may increase the risk of side effects while receiving NEXAVAR.

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. Never exceed the prescribed dose.

**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*)
- dry skin
- 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)

- a sudden, uncontrollable tightening of a muscle
- 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
- infection
- breathlessness
- inflamed or dry mouth, tongue pain

**Common side effects**

*(may affect 1 to 9 in every 100 people)*

- flushing
- acne
- flu-like illness
- inflammation at the base of hairs
- fever
- indigestion or heartburn
- difficulty swallowing
- voice changes
- underactive thyroid gland (hypothyroidism)
- skin cancer
- change in the sense of taste
- runny nose
- low blood levels of sodium
- 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
- life-threatening or fatal interstitial lung disease (changes within your lungs causing shortness of breath and coughing)
- increase in thyroid activity (may lead to nervousness, fast heart beat, anxiety, sweating and weight loss)

- severe 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
- inflammation of the liver
- inflammatory reaction of the skin in a body part previously exposed to radiation
- Inflammation of small blood vessels in the skin resulting in rash, erythema, and small blood spots under the skin (known as leukocytoclastic vasculitis). This condition may be painful, itchy or may not cause discomfort at all.
- Muscle problems including symptoms of unexplained muscle injury, such as muscle cramps, pain, tenderness, stiffness, weakness or spasm. This may be an early sign of a rare muscle problem (rhabdomyolysis) that could lead to serious kidney problems.
- changes in your blood tests may show:
  - low blood counts (white cells, red cells, or platelets) (leukopenia, neutropenia, anemia, thrombocytopenia)
  - temporary increase in certain liver tests (transient increase in transaminases)
  - low blood levels of calcium (hypocalcaemia)
  - low blood levels of potassium (hypokalemia)
  - abnormally high levels of protein in urine (proteinuria)
  - low or high levels of thyroid stimulating hormone (TSH) (hypothyroidism or hyperthyroidism)

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>		
Symptom/ Effect	Talk with your doctor or pharmacist	
	Only if severe	In all cases
<b>Very Common / Common</b>		
Rash including hives, redness or itching of your skin	✓	

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>		
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		✓
<b>Uncommon</b>		
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

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 at [www.healthcanada.gc.ca/medeffect](http://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 0701E
    - Ottawa, Ontario
    - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*Note: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

## MORE INFORMATION

For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or [canada.medinfo@bayer.com](mailto:canada.medinfo@bayer.com).

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.bayer.ca> or by contacting sponsor at the above-mentioned phone number and e-mail address.

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