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PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

Bayer (Pty) Ltd	**Date of revision of text: 22 April 2016**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME AND PHARMACEUTICAL FORM:

NEXAVAR® 200
Film-coated Tablets

Read all of this leaflet carefully before you start taking NEXAVAR® 200

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- NEXAVAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT NEXAVAR® 200 CONTAINS:

The active substance is sorafenib. 1 tablet contains 200 mg of sorafenib (274 mg sorafenib tosylate).
Other ingredients are: croscarmellose sodium, microcrystalline cellulose, hydroxypropylmethyl cellulose, sodium lauryl sulfate magnesium stearate, macrogol, titanium dioxide, iron oxide red.

2. WHAT NEXAVAR® 200 IS USED FOR:

NEXAVAR® 200 tablets are used to treat kidney cancer (renal cell carcinoma).
NEXAVAR® 200 tablets are used to treat liver cancer (hepatocellular carcinoma).
NEXAVAR® 200 tablets are used to treat thyroid cancer (*differentiated thyroid carcinoma*).
NEXAVAR® 200 is a *multikinase inhibitor.* It works by slowing down the growth of cancer cells and cutting off the blood supply that keeps cancer cells growing.

3. BEFORE YOU TAKE NEXAVAR® 200:

Do not take NEXAVAR®200:

- If you are allergic to sorafenib or any of the other components of Nexavar® 200 (see "What NEXAVAR® 200 contains").
- If you are pregnant or breastfeeding.

The safety and effectiveness of NEXAVAR® 200 in children has not been established**.**

Take special care with NEXAVAR® 200:

- If you experience skin problems.
  NEXAVAR® 200 can cause rashes and skin reactions, especially on the hands and feet. The skin changes generally appear during the first six weeks of treatment with NEXAVAR® 200. If you notice any changes, be sure to contact your doctor so he or she can begin treatment. Your doctor may recommend skin treatments, and/or a change in your dose of NEXAVAR® 200. If the skin changes do not go away, your doctor may stop your treatment with NEXAVAR® 200.
- If you have high blood pressure.
  NEXAVAR® 200 can raise blood pressure, and your doctor will monitor your blood pressure and may give you a medicine to treat high blood pressure.
- If you have bleeding problems or are taking treatment to prevent blood clots.
  Treatment with NEXAVAR® 200 may lead to a higher risk of bleeding. If you are taking warfarin or a medicine that thins the blood to prevent blood clots, there may be a greater

risk of bleeding.

- If you get chest pain or heart problems.
  Your doctor may decide to halt your treatment or stop it altogether.
- If you have an abnormality of your heart trace known as prolonged QT interval.
  NEXAVAR® 200 may affect your heart rhythm.
- If you are going to have surgery, or if you had an operation recently.
  NEXAVAR® 200 might affect the way your wounds heal. You will usually be taken off NEXAVAR® 200 if you are having an operation. Your doctor will decide when to start NEXAVAR® 200 again.
- If you have severe liver problems.
  You may experience more severe side effects when taking this medicine.
- If you have poor kidney function.
  Your doctor will monitor your fluid and electrolyte balance.
- When you have fertility problems.
  NEXAVAR® 200 may reduce fertility in both men and women. Ask your doctor for advice before taking NEXAVAR® 200.
- Holes in the gut (gastrointestinal perforation) may occur during treatment (see "Possible Side Effects"). In this case your doctor will interrupt the treatment.
- If you have thyroid cancer, your doctor will monitor blood calcium and thyroid hormone levels.

Tell your doctor if any of these affect you. You may need treatment for them, or your doctor may decide to change the dose of NEXAVAR® 200 or stop treatment altogether.

Pregnancy and Breastfeeding:

NEXAVAR® 200 should not be used during pregnancy. You should avoid becoming pregnant while taking NEXAVAR® 200. If you are able to bear children, you should use adequate contraception during treatment and for at least two weeks after completion. If you become pregnant while being treated with NEXAVAR® 200, immediately tell your doctor who will decide if treatment should be continued.

You must not breastfeed your baby during NEXAVAR® 200 treatment, as this medicine may interfere with the growth and development of your baby.

Driving and using machinery:
You may get disturbed sensations in fingers and toes, including tingling or numbness (sensory peripheral neuropathy) that may affect the ability to drive or to operate machinery.

Taking other medicines with NEXAVAR® 200:

If you are taking other medicines on a regular basis including complementary and traditional medicines, concomitant use of NEXAVAR® 200 may cause undesirable effects. Please inform your doctor or pharmacist of any other medication you may be taking.

If you are taking any of the following medicines please consult your healthcare professional:

- Rifampicin and Neomycin (antibiotics used to treat infections).
- St. John's Wort (a herbal treatment for depression).
- Phenytoin, Carbamazepine, Phenobarbital, treatments for epilepsy and other conditions.
- Dexamethasone (a corticosteroid used for various conditions).
- Ketoconazole (antifungal).
- Warfarin (anticoagulant used to prevent blood clots).
- Midazolam (benzodiazepine used to treat acute seizures, moderate to severe insomnia, and for inducing sedation during medical procedures).
- Dextromethorphan (cough suppressant).
- Omeprazole (used to treat gastrooesophageal reflux disease (GERD) and other conditions caused by excess stomach acid).

- Other cancer treatments such as Doxorubicin, Docetaxel, Paclitaxel, Carboplatin, Irinotecan, Capecitabine, Oxaliplatin.
- NEXAVAR® 200 may increase the effects and, in particular, the side effects of these anti-cancer medicines.

4. HOW TO TAKE NEXAVAR® 200:

Always take NEXAVAR® 200 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended daily dose of NEXAVAR® 200 is 2 tablets taken twice a day (every 12 hours), without food or together with a low fat or moderate fat meal. The tablets are to be taken orally with a glass of water.

Do not double the dose.

Do not share NEXAVAR® 200 that is prescribed for you with any other person.

The tablets should be swallowed whole with a glass of fluid; under no circumstances should it be bitten, chewed or broken up.

As far as possible, the treatment should be adapted according to the severity of your condition and your response. Do not change the dose prescribed by your doctor.

For how long should you take NEXAVAR® 200?

You will usually carry on taking NEXAVAR® 200 as long as you are benefitting, and not suffering unacceptable side effects. The attending doctor must decide on the length of the treatment.

If you take more NEXAVAR® 200 than you should:

Tell your doctor straight away if you take more than your prescribed dose.

If you forgot to take NEXAVAR® 200*:*

If you missed a dose, do not take more NEXAVAR® 200 tablets next time; simply continue the treatment as prescribed. Do not take a double does to make up for the missed dose.

What should you do if you want to interrupt the treatment or stop using NEXAVAR® 200 before the end of the course?

You should always consult your doctor before deciding to interrupt the course of treatment or stop taking NEXAVAR® 200 altogether.

5. POSSIBLE SIDE-EFFECTS:

NEXAVAR® 200 can have side effects. Not all side-effects reported for NEXAVAR® 200 are included in this leaflet. Should your general health worsen while taking NEXAVAR® 200, please consult your doctor, pharmacist or other health care professional for advice.

If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.

The most frequent side effects of NEXAVAR® 200 are: diarrhoea, nausea (feeling sick), tiredness (fatigue), vomiting (throwing up), dry skin, constipation, pain (including mouth, stomach, bone, joint and muscle pain), body rash, hair loss, bleeding, itching, decreased immunity, high blood pressure, congestive heart failure, depression, dry mouth, acne, fever, flu-like illness, weight loss, hoarseness of voice, kidney failure, low blood levels of calcium, low blood levels of potassium (hypokalaemia) and

abnormally high levels of protein in urine (proteinuria).

The frequent side effects of NEXAVAR® 200 are: heart attack and chest pain, congestive heart failure, loss of appetite, feeling weak, indigestion, difficulty in swallowing, inflamed, dry or scaly skin that sheds, disturbed sensations in fingers and toes, including tingling or numbness, impairment of sense of taste, flushing (sudden reddening of the face, neck, or upper chest), thickening of the outer layer of the skin on the palms and/or soles (hand foot reaction), muscle spasm, swelling of the mucous membranes, depression, erection problems, ringing in the ears, kidney failure.

The less frequent side effects of NEXAVAR® 200 are: abnormal heart tracing (ECG) (QT prolongation) and damage of the kidneys causing them to leak large amounts of protein (Nephrotic syndrome).

6. STORING AND DISPOSING OF NEXAVAR® 200:

Store at or below 30 ºC in a dry place. Store in the original container.
Store all medicines out of the reach of children.
Return unused or expired medicines to your pharmacist for safe disposal.

7. PRESENTATION OF NEXAVAR® 200:

Aluminium (Al) blister packs of 60 tablets, with each carton containing 6 blister strips of 10 tablets; or Aluminium (Al) blister packs of 112 tablets, with each carton containing 8 blister strips of 14 tablets.

8. IDENTIFICATION OF NEXAVAR® 200:

Red, round, biconvex film coated tablet. One side is embossed “BAYER” cross and the other “200”.

9. REGISTRATION NUMBER:

A40/26/0776

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd
Registration No.: 1968/011192/07
27 Wrench Road
ISANDO
1609

11. DATE OF PUBLICATION:

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