

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

SORAFENIB 200 DRL, 200 mg, film-coated tablets

Sorafenib

Sugar free

Each SORAFENIB 200 DRL film-coated tablet contains 200 mg of sorafenib
(274 mg sorafenib tosylate).

Read all of this leaflet carefully before you start taking SORAFENIB 200 DRL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SORAFENIB 200 DRL 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.

What is in this leaflet:

1. What SORAFENIB 200 DRL is and what it is used for
2. What you need to know before you take SORAFENIB 200 DRL
3. How to take SORAFENIB 200 DRL
4. Possible side effects

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

5. How to store SORAFENIB 200 DRL

6. Contents of the pack and other information

1. What SORAFENIB 200 DRL is and what it is used for

SORAFENIB 200 DRL is a so-called *multikinase inhibitor*. It works by slowing down the rate of growth of cancer cells and cutting off the blood supply that keeps cancer cells growing.

SORAFENIB 200 DRL tablets are used for the treatment of patients with advanced kidney cancer (renal cell carcinoma).

SORAFENIB 200 DRL are used for the treatment of patients with advanced inoperable liver cancer (hepatocellular carcinoma).

SORAFENIB 200 DRL tablets are used for the treatment of patients with thyroid cancer (differentiated thyroid carcinoma).

2. What you need to know before you take SORAFENIB 200 DRL

Do not take SORAFENIB 200 DRL:

- If you are hypersensitive (allergic) to sorafenib or any of the ingredients of SORAFENIB 200 DRL (listed in section 6).
- If you are a pregnant or breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before using SORAFENIB 200 DRL.

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

Take special care with SORAFENIB 200 DRL:

- **If you experience skin problems.** SORAFENIB 200 DRL can cause rashes and skin reactions, especially on the hands and feet. These can usually be treated by your doctor. If not, your doctor may interrupt treatment or stop it altogether.
- **If you have high blood pressure.** SORAFENIB 200 DRL can raise blood pressure, and your doctor will usually monitor your blood pressure and may give you a medicine to treat your high blood pressure.
- **If you have or have had an aneurysm** (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- **If you have diabetes.** Blood sugar levels in diabetic patients should be checked regularly in order to assess if anti-diabetic medicine's dosage needs to be adjusted to minimize the risk of low blood sugar.
- **If you get any bleeding problems, or are taking warfarin or phenprocoumon.** Treatment with SORAFENIB 200 DRL may lead to a higher risk of bleeding. If you are taking warfarin or phenprocoumon, medicines which thin 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 interrupt treatment or stop it altogether.
- **If you have a heart disorder**, such as an abnormal electrical signal called "prolongation of the QT interval".
- **If you are going to have surgery, or if you had an operation recently.**
SORAFENIB 200 DRL might affect the way your wounds heal. You will usually be

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

taken off SORAFENIB 200 DRL if you are having an operation.

Your doctor will decide when to start with SORAFENIB 200 DRL again.

- **If you are elderly.** Your doctor may consider monitoring your kidney function.
- **If you are taking irinotecan or are given docetaxel,** which are also medicines for cancer. SORAFENIB 200 DRL may increase the effects and, in particular, the side effects of these medicines.
- **If you are taking neomycin or other antibiotics.** The effect of SORAFENIB 200 DRL may be decreased.
- **If you have severe liver impairment.** 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.
- **Fertility.** SORAFENIB 200 DRL may reduce fertility in both men and women. If you are concerned, talk to a doctor.
- **Holes in the gut wall** (*gastrointestinal perforation*) may occur during treatment (see section 4: 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 your dose of SORAFENIB 200 DRL, or stop treatment altogether (see also section 4: Possible side effects).

Children and adolescents

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

Children and adolescents have not yet been tested with SORAFENIB 200 DRL.

Other medicines and SORAFENIB 200 DRL

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Some medicines may affect SORAFENIB 200 DRL, or be affected by it.

If you are taking any of the following medicines, please tell your doctor or pharmacist:

- Rifampicin, neomycin or other medicines used to treat infections (**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 or phenprocoumon, anticoagulants used to **prevent blood clots**
- Doxorubicin, capecitabine, docetaxel, paclitaxel, oxaliplatin and irinotecan, which are **cancer treatments**
- Digoxin, a treatment for mild to moderate **heart failure**

SORAFENIB 200 DRL with food and drink

- SORAFENIB 200 DRL can be taken either without food or together with a low fat or moderate fat meal.
- Do not take SORAFENIB 200 DRL with high fat meals.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

before taking SORAFENIB 200 DRL.

SORAFENIB 200 DRL should not be used during pregnancy. You should avoid becoming pregnant while taking SORAFENIB 200 DRL.

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 SORAFENIB 200 DRL, immediately tell your doctor who will decide if treatment should be continued.

You must not breastfeed your baby during SORAFENIB 200 DRL treatment, as SORAFENIB 200 DRL may interfere with the growth and development of your baby.

Driving and using machines

You may get distorted sensations in fingers and toes, including tingling or numbness (sensory peripheral neuropathy) that may affect your ability to drive or operate machinery.

It is not always possible to predict to what extent SORAFENIB 200 DRL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SORAFENIB 200 DRL affects them.

SORAFENIB 200 DRL contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".

3. HOW TO TAKE SORAFENIB 200 DRL

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

Do not share medicines prescribed for you with any other person.

Always take SORAFENIB 200 DRL exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The recommended daily dose of SORAFENIB 200 DRL in adults is 2 tablets taken twice a day, either without food or together with a low fat or moderate fat meal.

Do not take SORAFENIB 200 DRL with high fat meals, as this may make SORAFENIB 200 DRL less effective.

The tablet is taken orally with a glass of water.

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

It is important to take this medicine at about the same times each day, so that there is a steady amount in the bloodstream.

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.

You will usually carry on taking SORAFENIB 200 DRL as long as you are getting clinical benefits, and not suffering unacceptable side effects.

Your doctor will tell you how long your treatment with SORAFENIB 200 DRL will last.

You should not take SORAFENIB 200 DRL for longer than absolutely necessary.

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

If you take more SORAFENIB 200 DRL than you should

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

Taking too much SORAFENIB 200 DRL makes side effects more likely or more severe, especially diarrhoea and skin reactions.

If you forget to take SORAFENIB 200 DRL

If you missed a dose, do not take more SORAFENIB 200 DRL tablets next time; simply continue the treatment as prescribed.

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

What should you do if you want to interrupt the treatment or stop using

SORAFENIB 200 DRL before the end of the course

Do not interrupt the course of treatment or stop taking SORAFENIB 200 altogether unless you have discussed this with your doctor.

4. Possible side effects

SORAFENIB 200 DRL can have side effects.

Not all side effects reported for SORAFENIB 200 DRL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking SORAFENIB 200 DRL, please consult your health care provider for advice.

If any of the following happens, stop taking SORAFENIB 200 DRL and tell your doctor immediately or go to the casualty department at your nearest hospital:

Less frequent:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to SORAFENIB 200 DRL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- heart attack (*myocardial infarction*) or chest pain
- bleeding (including bleeding in the brain, gut wall and respiratory tract; *haemorrhage*)
- high blood pressure, or increases in blood pressure (*hypertension*)

Less frequent:

- abnormally high blood pressure
- inflammation of the liver, which may lead to nausea, vomiting, abdominal pain, and jaundice (*drug induced hepatitis*)
- serious reactions of the skin and/or mucous membranes which may include painful blisters and fever, including extensive detachment of the skin (*Stevens-Johnson syndrome and toxic epidermal necrolysis*)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor or pharmacist if you notice any of the following, especially if they continue, are severe or bother you:

Frequent:

- diarrhoea
- feeling sick (*nausea*)
- feeling weak or tired (*fatigue*)
- pain (including mouth pain, abdominal pain, headache, bone pain, tumour pain)
- hair loss (*alopecia*)
- flushed or painful palms or soles (*hand foot skin reaction*)
- itching or rash
- throwing up (*vomiting*)
- infections
- loss of appetite (*anorexia*)
- constipation
- joint pain (*arthralgia*)
- fever
- weight loss
- dry skin
- flu-like illness
- indigestion (*dyspepsia*)
- difficulty swallowing (*dysphagia*)
- inflamed or dry mouth, tongue pain (*stomatitis and mucosal inflammation*)

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

- low calcium levels in the blood (*hypocalcaemia*)
- low potassium levels in the blood (*hypokalaemia*)
- low blood sugar level (*hypoglycaemia*)
- muscle pain (*myalgia*)
- disturbed sensations in fingers and toes, including tingling or numbness
(*peripheral sensory neuropathy*)
- erection problems (*impotence*)
- altered voice (*dysphonia*)
- acne
- inflamed, dry or scaly skin that sheds (*dermatitis, skin desquamation*)
- heart failure
- tinnitus (*ringing sound in the ear*)
- kidney failure
- abnormally high levels of protein in the urine (*proteinuria*)
- general weakness or loss of strength (*asthenia*)
- decrease in the number of white blood cells (*leucopenia and neutropenia*)
- decrease in the number of red blood cells (*anaemia*)
- low number of platelets in the blood (*thrombocytopenia*)
- inflammation of hair follicles (*folliculitis*)
- underactive thyroid gland (*hypothyroidism*)
- low sodium levels in the blood (*hyponatraemia*)
- distortion of the sense of taste (*dysgeusia*)

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

- red in the face and often other areas of the skin (*flushing*)
- runny nose (*rhinorrhoea*)
- heartburn (*gastro oesophageal reflux disease*)
- skin cancer (*keratoacanthomas/squamous cell cancer of the skin*)
- a thickening of the outer layer of the skin (*hyperkeratosis*)
- a sudden, involuntary contraction of a muscle (*muscle spasms*)

Less frequent:

- inflamed stomach lining (*gastritis*)
- pain in the tummy (*abdomen*) caused by pancreatitis, inflammation of the gall bladder and/or bile ducts
- yellow skin or eyes (*jaundice*) caused by high levels of bile pigments (*hyperbilirubinaemia*)
- allergic like reactions (including skin reactions and hives)
- dehydration
- depression
- enlarged breasts (*gynaecomastia*)
- breathing difficulty (*lung disease*)
- eczema
- overactive thyroid gland (*hyperthyroidism*)
- multiple skin eruptions (*erythema multiforme*)
- holes in the gut wall (*gastrointestinal perforation*)
- reversible swelling in the rear part of the brain that can be associated with

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

headache, altered consciousness, fits and visual symptoms including visual loss
(*reversible posterior leukoencephalopathy*)

- a sudden, severe allergic reaction (*anaphylactic reaction*)
- allergic reaction with swelling of the skin (e. g. face, tongue) that may cause difficulty in breathing or swallowing (*angioedema*)
- abnormal heart rhythm (*QT prolongation*)
- a sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe (*radiation recall dermatitis*)
- abnormal muscle breakdown which can lead to kidney problems
(*rhabdomyolysis*)
- damage of the kidney causing them to leak large amounts of protein (*nephrotic syndrome*)
- inflammation of the vessels in the skin which may result in rash (*leucocytoclastic vasculitis*)

Frequency not known:

- impaired brain function that can be associated with e.g. drowsiness, behavioural changes, or confusion (*encephalopathy*)
- an enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (*aneurysms and artery dissections*).

If you notice any other side-effects not mentioned in this leaflet, please inform your doctor or your pharmacist.

Reporting of side effects

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of SORAFENIB 200 DRL.

5. How to store SORAFENIB 200 DRL

Store at or below 25 °C.

Keep blisters in the outer carton until required for use.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g. toilets).

Do not use after the expiry date stated on the carton.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What SORAFENIB 200 DRL contains

The active substance is sorafenib tosylate.

Each SORAFENIB 200 DRL film-coated tablet contains 200 mg of sorafenib (274 mg sorafenib tosylate).

The other ingredients are croscarmellose sodium, hypromellose, magnesium stearate, cellulose microcrystalline, silica colloidal anhydrous, sodium laurilsulfate and talc.

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

The film-coat ingredients are hypromellose, macrogol 3350, titanium dioxide and iron oxide red.

What SORAFENIB 200 DRL looks like and contents of the pack

SORAFENIB 200 DRL:

Red, round, biconvex, film-coated tablets, debossed with "S" on one side and plain on the other side.

Blister packs

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

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

Sandton

2057

South Africa

This leaflet was last revised in

08 October 2024

Registration number

56/26/1136

Access to the corresponding Professional Information

**APPROVED Patient information Leaflet:
Dr. Reddy's Laboratories (Pty) Ltd.
SORAFENIB 200 DRL (Film-coated tablets)**

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: <http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100