

RENOPLAST 200 mg FILM-COATED TABLETS

(Sorafenib)

Sorafenib (as tosylate) (200mg)

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What *RENOPLAST* is used for

RENOPLAST is used to treat liver cancer (hepatocellular carcinoma). *RENOPLAST* is also used to treat kidney cancer (advanced renal cell carcinoma) at an advanced stage when standard therapy has not helped to stop your disease or is considered unsuitable. *RENOPLAST* is used to treat thyroid cancer (differentiated thyroid carcinoma).

How *RENOPLAST* works

RENOPLAST 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

Before you use *RENOPLAST*

-When you must not use it:

- If you are allergic to sorafenib or any of the other ingredients of this medicine

-Before you start to use it:

Talk to your doctor or pharmacist before taking *RENOPLAST*.

Take special care with *RENOPLAST*

- If you experience skin problems. *RENOPLAST* 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. *RENOPLAST* 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 *RENOPLAST* 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. *RENOPLAST* might affect the way your wounds heal. You will usually be taken off *RENOPLAST* if you are having an operation. Your doctor will decide when to start with *RENOPLAST* again.

- If you are taking irinotecan or are given docetaxel, which are also medicines for cancer. *RENOPLAST* may increase the effects and, in particular, the side effects of these medicines.

- If you are taking Neomycin or other antibiotics. The effect of *RENOPLAST* 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. *RENOPLAST* 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. 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 *RENOPLAST*, or stop treatment altogether.

Children and adolescents

Children and adolescents have not yet been tested with *RENOPLAST*.

-Taking other medicines:

Some medicines may affect *RENOPLAST*, or be affected by it. Tell your doctor or pharmacist if you are taking, have recently taken or might take anything in this list or any other medicines, including medicines obtained without a prescription:

- 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 and irinotecan, which are cancer treatments
- Digoxin, a treatment for mild to moderate heart failure

How to use *RENOPLAST*

Swallow *RENOPLAST* tablets with a glass of water, either without food or with a low-fat or moderate fat meal. Do not take this medicine with high fat meals, as this may make *RENOPLAST* less effective. If you intend to have a high fat meal, take the tablets at least 1 hour before or 2 hours after the meal. Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure

-How much to use

The recommended dose of *RENOPLAST* in adults is 2 x 200 mg tablets, twice daily.

This is equivalent to a daily dose of 800 mg or four tablets a day.

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-When to use it

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

-How long to use it

You will usually carry on taking this medicine as long as you are getting clinical benefits, and not suffering unacceptable side effects

-If you forget to use it

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

-If you use too much (overdose)

Tell your doctor straight away if you (or anyone else) have taken more than your prescribed dose. Taking too much RENOPLAST makes side effects more likely or more severe, especially diarrhoea and skin reactions. Your doctor may tell you to stop taking this medicine.

If you stop using RENOPLAST

Your doctor will decide when you should stop your treatment. However, if you want to stop your treatment earlier, you should discuss other options with your doctor.

While you are using it

- Things you must do

Take the medicine as decided by your doctor

- Things you must not do

Pregnancy and breast-feeding

Avoid becoming pregnant while being treated with RENOPLAST. If you could become pregnant use adequate contraception during treatment. If you become pregnant while being treated with RENOPLAST, immediately tell your doctor who will decide if the treatment should be continued.

You must not breast-feed your baby during RENOPLAST treatment, as this medicine may interfere with the growth and development of your baby

• Things to be careful of

Driving and using machines

There is no evidence that RENOPLAST will affect the ability to drive or to operate machines.

Side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. This medicine may also affect the results of some blood tests.

Very common:

- 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)
- bleeding (including bleeding in the brain, gut wall and respiratory tract; haemorrhage)
- high blood pressure, or increases in blood pressure (hypertension)
- infections
- loss of appetite (anorexia)
- constipation
- joint pain (arthralgia)
- fever
- weight loss
- dry skin

Common:

- flu-like illness
- indigestion (dyspepsia)
- difficulty swallowing (dysphagia)
- inflamed or dry mouth, tongue pain (stomatitis and mucosal inflammation)
- 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)
- depression
- erection problems (impotence)
- altered voice (dysphonia)
- acne
- inflamed, dry or scaly skin that sheds

(dermatitis, skin desquamation)

- heart failure
- heart attack (myocardial infarction) or chest pain
- 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)
- 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)

Uncommon:

- 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
- enlarged breasts (gynaecomastia)
- breathing difficulty (lung disease)
- eczema
- overactive thyroid gland (hyperthyroidism)
- multiple skin eruptions (erythema multiforme)
- abnormally high blood pressure
- holes in the gut wall (gastrointestinal

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perforation)

- reversible swelling in the rear part of the brain that can be associated with headache, altered consciousness, fits and visual symptoms including visual loss (reversible posterior leukoencephalopathy)
- a sudden, severe allergic reaction (anaphylactic reaction)

Rare

- 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)
- inflammation of the liver, which may lead to nausea, vomiting, abdominal pain, and jaundice (drug induced hepatitis)
- a sunburn-like rash that may occur on skin that has previously been exposed to radiotherapy and can be severe (radiation recall dermatitis)
- 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)
- 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)

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).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines

(AEFI)]

Storage and Disposal of RENOPLAST

- Storage

Keep this medicine out of the sight and reach of children.
Do not store above 30°C..

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Red-brown, round, biconvex film-coated tablets, debossed with “200” on one side and plain on the other side.

Ingredients

-Active ingredient:

200 mg of sorafenib (as tosylate).

-Inactive ingredients:

Hypromellose HPMC 2910, Croscarmellose Sodium, Microcrystalline cellulose, magnesium stearate, sodium lauryl sulfate, Titanium dioxide, Macrogol & Red Iron Oxide

MAL Numbers :

MAL23046035ACZ

Manufacturer

PharOs MT Ltd,
HF62X, Hal Far Industrial Estate,
Birzebbugia, BBG3000, Malta.

Product Registration Holder

Lotus Healthcare Malaysia Sdn. Bhd,
UOA BUSINESS PARK, TOWER 3,
9TH FLOOR, K03-09-11,
1 JALAN PENGATURCARA
U1/51A,
SECTION U1, 40150 SHAH ALAM
SELANGOR,
MALAYSIA

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