

**APPROVED PATIENT INFORMATION LEAFLET
DR. REDDY'S LABORATORIES (PTY) LTD
NILOTINIB 150 DRL & NILOTINIB 200 DRL
(nilotinib)
Capsules**

SCHEDULING STATUS

S4

NILOTINIB 150 DRL, capsules

NILOTINIB 200 DRL, capsules

Nilotinib

Contains sugar:

NILOTINIB 150 DRL: 116,87mg of lactose

NILOTINIB 200 DRL: 155,83 mg of lactose

Read all of this leaflet carefully before you start taking NILOTINIB 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.
- NILOTINIB 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.

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What is in this leaflet

1. What NILOTINIB DRL is and what it is used for
2. What you need to know before you use NILOTINIB DRL
3. How to use NILOTINIB DRL
4. Possible side effects
5. How to store NILOTINIB DRL
6. Contents of the pack and other information

1. What NILOTINIB DRL is and what it is used for

NILOTINIB DRL is a medicine that contains the active substance nilotinib.

NILOTINIB DRL is used to treat a type of leukaemia called Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML). CML is a cancer of the blood which makes the body produce too many abnormal white blood cells.

NILOTINIB DRL is used in patients with newly diagnosed CML or patients with CML who are no longer benefiting from previous treatment. It is also used in patients who experienced serious side-effects with previous treatment and are not able to continue taking it.

2. What you need to know before you take NILOTINIB DRL

Do not take NILOTINIB DRL if you:

- are hypersensitive (allergic) to nilotinib or any of the ingredients of NILOTINIB DRL (See Section 6).

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Warnings and precautions

Take special care with NILOTINIB DRL

Tell your doctor or healthcare professional before taking NILOTINIB DRL:

- if you have heart problems, including a heart attack, chest pain (angina), problems with your brain blood supply (stroke), or problems with your leg blood flow (claudication) or if you have risk factors for cardiovascular disease such as high blood pressure (hypertension), diabetes, or problems with the level of fats in your blood (lipid disorders) or if you are a smoker.
- if you have a heart disorder, such as an abnormal electrical signal called “prolongation of the QT interval”.
- if you are being treated with medicines that affect the heartbeat (antidysrhythmics) or the liver (see “Other medicines and NILOTINIB DRL”).
- If you have ever had or might now have a hepatitis B infection. This is because during treatment with NILOTINIB DRL, hepatitis B may become active again. Your doctor will check for signs of this infection before treatment with NILOTINIB DRL is started.
- if you suffer from a low level of calcium or magnesium in your blood.
- If you suffer from either high or low levels of potassium in the blood.
- if you have had pancreatitis (inflamed pancreas).
- you have liver problems.
- if you have had a surgical procedure involving the removal of the entire stomach (total gastrectomy).
- if you experience nausea, vomiting, diarrhoea, muscle cramps or twitches, weakness, numbness or tingling, tiredness, decreased urination (these are symptoms of tumour lysis syndrome).

During treatment with NILOTINIB DRL

NILOTINIB DRL should not be used as first line therapy in patients with prior severe peripheral arterial occlusive disease (PAOD). Call your doctor right away or as soon as possible if you faint (loss of consciousness) or have an irregular pulse while taking NILOTINIB DRL as these may be due to a serious

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heart condition.

Call your doctor right away or as soon as possible if you develop chest pain or discomfort, numbness or weakness or problems with gait or speech, or pain, numbness, discoloration or a cool feeling in a limb.

Call your doctor right away or as soon as possible if you develop fever, skin rash, joint pain and inflammation as well as tiredness, loss of appetite, nausea, jaundice (yellowing of the skin), stomach pain, pale stools and dark urine (potential signs of hepatitis B reactivation).

If any of these apply to you, tell your doctor before taking NILOTINIB DRL.

Other medicines and NILOTINIB DRL

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

(This includes complementary or traditional medicines).

Tell your doctor or pharmacist before taking NILOTINIB DRL if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- ketoconazole, itraconazole, voriconazole, clarithromycin, telithromycin - used to treat fungal and bacterial infections;
- ritonavir - an anti-HIV medicine from the class protease inhibitors;
- carbamazepine, phenobarbital, phenytoin - used to treat epilepsy;
- rifampicin - used to treat tuberculosis;
- St. John's Wort - a herbal product used to treat depression (also known as *Hypericum perforatum*);
- midazolam - used to relieve anxiety;
- warfarin - used to treat blood coagulation disorders (such as blood clots or thromboses)
- alfentanil and fentanyl - used to treat pain and used as a sedative before or during surgery or medical procedure;
- ciclosporin, sirolimus and tacrolimus - medicines that suppress the "self-defence" ability of the body

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and fight infections - commonly used to prevent the rejection of transplanted organs such as liver, heart and kidney;

- dihydroergotamine and ergotamine – used to treat migraine;
- lovastatin, simvastatin – used to treat high level of fats in blood;
- antidysrhythmics e.g., amiodarone, disopyramide, procainamide, quinidine and sotalol - used to treat irregular heartbeat.
- chloroquine, halofantrine, clarithromycin, haloperidol, methadone, moxifloxacin – medicines that may have an unwanted effect on the function of the heart.

These medications should be avoided during your treatment with NILOTINIB DRL.

If you are taking any of these, your doctor might prescribe other medicines.

Taking NILOTINIB DRL with food and drink

Do not take NILOTINIB DRL with food.

Take the capsules at least two hours after any food and then wait at least one hour before eating again.

Do not drink grapefruit juice or eat grapefruit while on NILOTINIB DRL. It may increase the amount of NILOTINIB DRL in the blood, possibly to a harmful level.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby while taking NILOTINIB DRL, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

- NILOTINIB DRL should not be used in women in their fertile years unless adequate contraceptive measures are taken.
- Women of child-bearing potential or sexually active men must use effective birth control while taking NILOTINIB DRL and for up to two weeks after ending treatment.
- Breastfeeding is not recommended during treatment with NILOTINIB DRL. Tell your doctor if you are

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breastfeeding.

Driving and using machines

If you experience side effects (such as dizziness or visual disorders) with a potential impact on the ability to safely drive or use any tools or machines after taking NILOTINIB DRL, you should refrain from these activities.

It is not always possible to predict to what extent NILOTINIB 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 NILOTINIB DRL affects them.

Use in children and adolescents

There is no experience with the use of NILOTINIB DRL in children and adolescents and hence should not be used by these patients.

Use in elderly

NILOTINIB DRL can be used by people aged 65 years and over at the same dose as for other adults.

NILOTINIB DRL contains lactose

NILOTINIB DRL contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NILOTINIB DRL.

3. How to take NILOTINIB DRL

Always take NILOTINIB DRL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Do not share medicines prescribed for you with others.

Your doctor will tell you how long your treatment with NILOTINIB DRL will last. Do not stop treatment early. If

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you have the impression that the effect of NILOTINIB DRL is too strong or too weak, tell your doctor or pharmacist.

Monitoring your NILOTINIB DRL treatment

You will have regular tests including blood tests during treatment. These will monitor the amount of blood cells (white blood cells, red blood cells and platelets) in your body to see how NILOTINIB DRL is tolerated. Blood tests will also monitor the electrolytes in your body (potassium, magnesium); these are important in the functioning of your heart. Your heart will be checked using a machine that measures electrical activity of the heart (a test called "ECG"). Blood tests will also monitor the level of sugar and fats (cholesterol) in your blood.

Your doctor may also consider prescribing uric acid lowering medicines for you if necessary. Your doctor may consider discontinuing your treatment with NILOTINIB DRL based on specific criteria.

If you have any questions about how NILOTINIB DRL works or why it has been prescribed for you, ask your doctor.

How much NILOTINIB DRL to take

The usual starting dose is 2 capsules twice a day of either 150 mg or 200 mg depending on your exact condition. Always take NILOTINIB DRL exactly as your doctor has told you.

When to take NILOTINIB DRL

Take the capsules twice a day (approximately every 12 hours), at least 2 hours after any food. Then wait for at least 1 hour before eating again.

If you have questions about when to take NILOTINIB DRL, talk to your doctor or pharmacist.

Taking NILOTINIB DRL at the same time each day will help you remember when to take your capsules.

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How to take NILOTINIB DRL

Do not take any food together with the capsules.

Swallow the capsules whole with water.

For patients who are unable to swallow capsules, the content of each capsule may be dispersed in one teaspoon of applesauce (pureed apple) and be taken immediately.

Not more than one teaspoon of applesauce and no food other than applesauce must be used.

If you take more NILOTINIB DRL than you should

If you have taken more NILOTINIB DRL than you should have, or if someone else accidentally takes your capsules, contact a doctor or the hospital for advice straight away. Show them the pack of capsules. Medical treatment may be necessary.

If you forget to take NILOTINIB DRL

If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for the forgotten capsules.

If you stop taking NILOTINIB DRL

Do not stop taking NILOTINIB DRL unless your doctor tells you to. If you have any further questions on the use of NILOTINIB DRL, ask your doctor or pharmacist.

If your doctor recommends that you discontinue treatment with NILOTINIB DRL

Your doctor will regularly evaluate your treatment with a specific diagnostic test and decide whether you should continue to take NILOTINIB DRL. If you are told to discontinue NILOTINIB DRL your doctor will continue to carefully monitor your CML before, during and after you have discontinued NILOTINIB DRL and

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may tell you to re-start NILOTINIB DRL if your condition indicates that this is necessary.

4. Possible side effects

NILOTINIB DRL can have side effects.

Not all side effects reported for NILOTINIB DRL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NILOTINIB DRL, please consult your doctor, pharmacist or other health care professional for advice.

Some side effects can be serious:

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

- allergic reactions including swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing, throat tightness.
- shortness of breath and wheezing.
- rash, hives (raised bumps), blisters or itching.
- allergic reactions, including death, can happen in patients taking NILOTINIB DRL even after only one dose.
- frequent infections.
- a serious condition in which the body responds improperly to an infection.
- reactivation of hepatitis B infection when you have had hepatitis B (an infection of the liver) in the past.
- chest pain or discomfort, high blood pressure, irregular heart rhythm.
- pain resulting from not enough blood flowing to the heart (angina pectoris).
- heart failure.
- compression of the heart by an accumulation of fluid in the pericardial sac (cardiac tamponade).
- weakness or paralysis of limbs or face, difficulty speaking, severe headache.

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- yellow skin and eyes, nausea, loss of appetite, light-coloured urine.

Tell your doctor if you notice any of the following:

Frequent side effects:

- inflammation of hair follicles, lung infection, nasal congestion, runny nose, sneezing.
- warts on the skin.
- low level of white blood cells (changes in blood test results).
- low levels of phosphate, magnesium, potassium, salt, calcium (picked up in blood tests).
- high levels of potassium, calcium, sugar, cholesterol (picked up in blood tests).
- decreased appetite.
- feeling sad (depression) and anxious, insomnia (sleeplessness).
- dizziness, tingling or numbness, reduced sense of touch.
- bleeding and swelling in the eye, dry and itchy eyes.
- spinning sensation (vertigo).
- flushing, high blood pressure.
- shortness of breath, nose bleeds, cough, voice disorder (weak or hoarse voice).
- stomach discomfort, bloating, indigestion, disturbed sense of taste (e.g., metallic taste), sensation persists in the mouth, gas.
- liver problems.
- night sweats, excessive sweating, pimples (acne), "hives".
- muscle pain and weakness, back pain.
- frequent, abnormal urination during the day, kidney problems.

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- increased weight, abnormal blood test results.

Less frequent side effects:

- various types of infections e.g., urinary tract, thrush.
- high or low levels of thyroid hormone.
- pain and swelling of your big toe (gout), feeling very thirsty, increase in appetite.
- blurred vision, eye irritation, swelling, discharge, itching or redness, dry eye (signs of eye disorders).
- lung problems, throat irritation.
- heartburn, swelling or bloating of the abdomen, sensitivity of teeth.
- muscle stiffness and swelling of the joints.
- difficulty and pain when passing urine, exaggerated sense of needing to urinate, when you wake up more than one time each night to go to the bathroom.
- breast pain, inability to achieve or maintain an erection.
- breast enlargement in men.
- feeling body temperature change (including feeling hot, feeling cold).

During NILOTINIB DRL treatment, you may also have some abnormal blood test results such as low level of blood cells (white cells, red cells, platelets), high blood level of lipase or amylase, urea, lactate dehydrogenase.

Side effects of an unknown frequency:

- virus that affects the mouth, tongue, lips.
- inflammation of thyroid gland.

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- high levels of uric acid and low levels of sugar (picked up in blood tests).
- confusion, disorientation, memory loss, a mental state in which you have a profound sense of unease or dissatisfaction.
- tiredness, an unpleasant, abnormal sense of touch, a condition that causes an uncontrollable urge to move the legs.
- swelling of the eye due to increased pressure in the eye, double vision, sensitivity to the light, inflammation of the eyelids, eye pain, eye inflammation caused by an allergic reaction.
- difficulty hearing, ear pain, ringing in the ears.
- shock as a result of severe bleeding, low blood pressure, blood clots in veins and arteries, the narrowing or blockage of the vessels that carry blood from the heart to the legs.
- wheezing, mouth pain.
- ulcers, vomiting blood, the upper part of your stomach bulges through your diaphragm into your chest cavity (hiatus hernia), swollen veins in your lower rectum (haemorrhoids), bleeding in the rectum, sensitivity of your teeth, inflammation of the gums.
- decrease in bile production and flow, enlargement of the liver.
- skin ulcers, blisters, skin discolouration and peeling, increased sensitivity of the eyes or the skin to light; thickened patches of red/silver skin (signs of psoriasis).
- swelling of the joints.
- blood in the urine, abnormal colour of the urine, you have a sudden, intense urge to urinate followed by an involuntary loss of urine.
- thickening and hardening of the breast tissue, heavy or prolonged menstrual bleeding, swelling of the nipples.
- swelling of certain parts of your body.

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If you notice any side effects not on this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via 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 NILOTINIB DRL.

5. How to store NILOTINIB DRL

Store at or below 25 °C.

Keep in the original package to protect it from moisture.

Return all unused medicine to your pharmacist.

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

Do not use NILOTINIB DRL after the expiry date printed on the carton.

Keep all medicines out of reach and sight of children.

6. Contents of the pack and other information

What NILOTINIB DRL contains

The active substance is nilotinib.

The other ingredients are colloidal silicon dioxide, crospovidone, lactose monohydrate, magnesium stearate, poloxamer, purified water. The capsule shell is composed of ferric oxide, red, ferric oxide, yellow, gelatin, purified water, S.L.S, titanium dioxide. The printing ink contains iron oxide, black.

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What NILOTINIB DRL looks like and contents of the pack

NILOTINIB 150 DRL: White to pale yellow coloured granular powder filled in capsule shell with red opaque coloured cap and body imprinted with RDY on cap and 150 on body in black ink. Free from physical defects.

NILOTINIB 200 DRL: White to pale yellow coloured granular powder filled in capsule shell with light yellow opaque coloured cap and body imprinted with RDY on cap and 200 on body in black ink. Free from physical defects.

NILOTINIB DRL is supplied in packs of 28, 30, 112 or 120 in clear PVC/PVdC (polyvinylchloride/polyvinylidene chloride) blisters with an aluminium foil backing.

The blisters are packed into cardboard cartons.

Not all pack sizes may be available.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

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2057

This leaflet was last revised in

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Registration numbers

NILOTINIB 150 DRL: 59/26/0508

NILOTINIB 200 DRL: 59/26/0509

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Access to the corresponding Professional Information

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