Nilotinib DRL hard capsules

Nilotinib (150mg and 200mg)

What is in this leaflet

What Nilotinib DRL is used for

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

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

How Nilotinib DRL works

In patients with CML, a change in DNA (genetic material) triggers a signal that tells the body to produce abnormal white blood cells. Nilotinib DRL blocks this signal, and thus stops the production of these cells.

Monitoring during Nilotinib DRL treatment Regular tests, including blood tests, will be performed during treatment. These tests 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.
- pancreas and liver function in the body to see how Nilotinib DRL is tolerated.
- the electrolytes in the body (potassium, magnesium). These are important in the functioning of the heart.
- the level of sugar and fats in the blood.

The heart rate will also be checked using a machine that measures electrical activity of the heart (a test called an "ECG").

Your doctor will regularly evaluate your treatment and decide whether you should continue to take Nilotinib DRL. If you are told to discontinue this medicine, your doctor will continue to monitor your CML and may tell you to re-start Nilotinib DRL if your condition indicates that this is necessary.

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

Before you use Nilotinib DRL

Follow all the doctor's instructions carefully. They may differ from the general information contained in this leaflet.

When you must not use it

If you are allergic to nilotinib or any of the other ingredients of this medicine (listed at *Ingredients* under Product Description). If you think you may be allergic, tell your doctor before taking Nilotinib DRL.

Pregnancy and breast-feeding

- Nilotinib DRL is not recommended during pregnancy unless clearly necessary. If you are pregnant or think that you may be, tell your doctor who will discuss with you whether you can take this medicine during your pregnancy.
- Women who might get pregnant are advised to use highly effective contraception during treatment and for up to two weeks after ending treatment.
- Breast-feeding is not recommended during treatment with Nilotinib DRL and for two weeks after the last dose. Tell your doctor if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Before you start to use it

Talk to your doctor or pharmacist before taking Nilotinib DRL:

- if you have suffered prior cardiovasuclar events such as a heart attack, chest pain (angina), problems with the blood supply to your brain (stroke) or problems with the blood flow to your leg (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).
- 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 heart beat (anti- arrhythmics) or the liver (see *Taking other medicines*).
- if you suffer from lack of potassium or magnesium.
- if you have a liver or pancreas disorder.
- if you have symptoms such as easy bruising, feeling tired or short of breath or have experienced repeated infections.
- if you have had a surgical procedure involving the removal of the entire stomach (total gastrectomy).
- if you have ever had or might now have a hepatitis B infection. This is because Nilotinib DRL could cause hepatitis B to become active again, which can be fatal in some cases. Patients will be carefully checked by their doctor for signs of this infection before treatment is started.

If any of these apply to you or your child, tell your doctor.

Children and adolescents

Nilotinib DRL is a treatment for children and adolescents with CML. There is no experience with the use of this medicine in children below 2 years of age. There is no experience with the use of Nilotinib DRL in newly diagnosed children below 10 years of age and limited experience in patients below 6 years of age who are no longer benefiting from previous treatment for CML. The long-term effects of treating children with Nilotinib DRL for long periods of time are not known.

Some children and adolescents taking Nilotinib DRL may have slower than normal growth. The doctor will monitor growth at regular visits.

Taking other medicines

Nilotinib DRL may interfere with some other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes in particular:

- antiarrhythmics – used to treat irregular heart beat;
- chloroquine, halofantrine, clarithromycin, haloperidol, methadone, moxifloxacin -

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medicines that may have an unwanted effect on the electrical activity of the heart;
- ketoconazole, itraconazole, voriconazole, clarithromycin, telithromycin – used to treat infections;
- ritonavir – a medicine from the class " antiproteases" used to treat HIV;
- carbamazepine, phenobarbital, phenytoin – used to treat epilepsy;
- rifampicin – used to treat tuberculosis;
- St. John's Wort – a herbal product used to treat depression and other conditions (also known as *Hypericum perforatum*);
- midazolam – used to relieve anxiety before surgery;
- alfentanil and fentanyl – used to treat pain and as a sedative before or during surgery or medical procedures;
- cyclosporine, sirolimus and tacrolimus – medicines that suppress the "self-defence" ability of the body and fight infections and are commonly used to prevent the rejection of transplanted organs such as the liver, heart and kidney;
- dihydroergotamine and ergotamine – used to treat migraine;
- lovastatin, simvastatin – used to treat high level of fats in blood;
- warfarin – used to treat blood coagulation disorders (such as blood clots or thromboses);
- astemizole, terfenadine, cisapride, pimozide, quinidine, bepridil or ergot alkaloids (ergotamine, dihydroergotamine).

These medicines should be avoided during your treatment with Nilotinib DRL. If you are taking any of these, your doctor might prescribe other alternative medicines.

In addition, tell your doctor or pharmacist before taking Nilotinib DRL if you are taking any antacids, which are medicines against heartburn. These medicines need to be taken separately from Nilotinib DRL:
- H2 blockers, which decrease the production of acid in the stomach. H2 blockers should be taken approximately 10 hours before and approximately 2 hours after you take Nilotinib DRL;
- antacids such as those containing aluminium hydroxide, magnesium hydroxide and simethicone, which neutralise high acidity in the stomach. These antacids should be taken approximately 2 hours before or approximately 2 hours after you take Nilotinib DRL.

You should also tell your doctor if you are already taking Nilotinib DRL and you are prescribed a new medicine that you have not taken previously during Nilotinib DRL treatment.

Taking Nilotinib DRL with food and drink

Do not take Nilotinib DRL with food. Food may enhance the absorption of Nilotinib DRL and therefore increase the amount of Nilotinib DRL in the blood, possibly to a harmful level. Do not drink grapefruit juice or eat grapefruit. It may increase the amount of Nilotinib DRL in the blood, possibly to a harmful level.

How to use Nilotinib DRL

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

Use in adults

Patients newly diagnosed with CML: The recommended dose is 600 mg per day. This dose is achieved by taking two hard capsules of 150 mg twice a day.

Patients who are no longer benefiting from previous treatment for CML: The recommended dose is 800 mg per day. This dose is achieved by taking two hard capsules of 200 mg twice a day.

Use in children and adolescents

The dose given to your child will depend on your child's body weight and height. The doctor will calculate the correct dose to use and tell you which and how many capsules of Nilotinib DRL to give to your child. The total daily dose you give to your child must not exceed 800 mg.

Your doctor may prescribe a lower dose depending on how you respond to treatment.

Older people (age 65 years and over)

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

When to use it

Take the hard capsules:
- twice a day (approximately every 12 hours);
- at least 2 hours after any food; then wait 1 hour before eating again. If you have questions about when to take this medicine, talk to your doctor or pharmacist. Taking Nilotinib DRL at the same time each day will help you remember when to take your capsules.

How to use Nilotinib DRL

- Swallow the hard capsules whole with water.
- Do not take any food together with the hard capsules.
- In case of difficulty swallowing the hard capsules, including children and adolescents, other medicines containing Nilotinib should be used instead of Nilotinib DRL product.

How long to use it

Continue taking Nilotinib DRL every day for as long as your doctor tells you. This is a long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.
If you have questions about how long to take Nilotinib DRL, talk to your doctor.

If you forget to use 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 use too much (overdose)

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

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 this medicine. If you are told to discontinue this medicine, your doctor will continue to monitor your CML and may tell you to re-start Nilotinib DRL if your condition indicates that this is necessary.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While you are using Nilotinib DRL

Things you must do

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During treatment with Nilotinib DRL:
- If you faint (loss of consciousness) or have an irregular heart beat while taking this medicine, tell your doctor immediately as this may be a sign of a serious heart condition.
Prolongation of the QT interval or an irregular heart beat may lead to sudden death. Uncommon cases of sudden death have been reported in patients taking Nilotinib DRL.
- if you have sudden heart palpitations, severe muscle weakness or paralysis, seizures or sudden changes in your thinking or level of alertness, tell your doctor immediately as this may be a sign of a fast breakdown of cancer cells called tumour lysis syndrome. Rare cases of tumour lysis syndrome have been reported in patients treated with Nilotinib DRL.
- if you develop chest pain or discomfort, numbness or weakness, problems with walking or with your speech, pain, discolouration or a cool feeling in a limb, tell your doctor immediately as this may be a sign of a cardiovascular event.
Serious cardiovascular events including problems with the blood flow to the leg (peripheral arterial occlusive disease), ischaemic heart disease and problems with the blood supply to the brain (ischaemic cerebrovascular disease) have been reported in patients taking Nilotinib DRL. Your doctor should assess the level of fats (lipids) and sugar in your blood before initiating treatment with Nilotinib DRL and during treatment.
- if you develop swelling of the feet or hands, generalised swelling or rapid weight gain tell your doctor as these may be signs of severe fluid retention.
Uncommon cases of severe fluid retention have been reported in patients treated with Nilotinib DRL.
If you are the parent of a child who is being treated with Nilotinib DRL, tell the doctor if any of the above conditions apply to your child.

Things you must not do
Do not stop taking this medicine unless your doctor tells you to. Stopping Nilotinib DRL without your doctor's recommendation places you at risk for worsening of your disease which could have life-threatening consequences. Be sure to discuss with your doctor, nurse, and/or pharmacist if you are considering stopping Nilotinib DRL.

Things to be careful of
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 this medicine, you should refrain from these activities until the effect has disappeared.

Nilotinib DRL contains lactose
This medicine contains lactose (also known as milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. Most of the side effects are mild to moderate and will generally disappear after a few days to a few weeks of treatment.

Some side effects could be serious.
These side effects are very common (may affect more than 1 in 10 people), common (may affect up to 1 in 10 people), uncommon (may affect up to 1 in 100 people) or have been reported with frequency not known (cannot be estimated from the available data):
- rapid weight gain, swelling of hands, ankles, feet or face (signs of water retention)
- chest pain or discomfort, high or low blood pressure, irregular heart rhythm (fast or slow), palpitations (sensation of rapid heartbeat), fainting, blue discolouration of the lips, tongue or skin (signs of heart disorders)
- difficulty breathing or painful breathing, cough, wheezing with or without fever, swelling of the feet or legs (signs of lung disorders)
- fever, easy bruising or unexplained bleeding, severe or frequent infections, unexplained weakness (signs of blood disorders)
- weakness or paralysis of the limbs or face, difficulty speaking, severe headache, seeing, feeling or hearing things that are not there, changes in eyesight, loss of consciousness, confusion, disorientation, trembling, sensation of tingling, pain or numbness in fingers and toes (signs of nervous system disorders)
- thirst, dry skin, irritability, dark urine, decreased urine output, difficulty and pain when urinating, exaggerated sense of needing to urinate, blood in urine, abnormal urine colour (signs of kidney or urinary tract disorders)
- visual disturbances including blurred vision, double-vision or perceived flashes of light, decreased sharpness or loss of vision, blood in eye, increased sensitivity of the eyes to light, eye pain, redness, itching or irritation, dry eye, swelling or itching of the eyelids (signs of eye disorders)
- swelling and pain in one part of the body (signs of clotting within a vein)
- abdominal pain, nausea, vomiting of blood, black or bloody stools, constipation, heartburn, stomach acid reflux, swollen abdomen (signs of gastrointestinal disorders)
- severe upper (middle or left) abdominal pain (sign of pancreatitis)
- yellow skin and eyes, nausea, loss of appetite, dark-coloured urine (signs of liver disorders)
- painful red lumps, skin pain, skin reddening, peeling or blisters (signs of skin disorders)
- pain in joints and muscles (signs of musculoskeletal pain)
- excessive thirst, high urine output, increased appetite with weight loss, tiredness (signs of high level of sugar in the blood)
- fast heartbeat, bulging eyes, weight loss, swelling at the front of the neck (signs of overactive thyroid gland)
- weight gain, tiredness, hair loss, muscle weakness, feeling cold (signs of underactive thyroid gland)
- severe headache often accompanied by nausea, vomiting and sensitivity to light (signs of migraine)
- dizziness or spinning sensation (signs of vertigo)
- nausea, shortness of breath, irregular heartbeat, clouding of urine, tiredness and/or joint discomfort associated with abnormal results of blood tests (such as high levels of potassium, uric acid and phosphorous and low levels of calcium)
- pain, discomfort, weakness or cramping in the leg muscles, which may be due to decreased blood flow, ulcers on the legs or arms that heal slowly or not at all and noticeable changes in colour (blueness or paleness) or

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temperature (coolness) of the legs or arms, as these symptoms could be signs of artery blockage in the affected limb (leg or arm) and digits (toes or fingers)
- recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection).

Some side effects are very common *(may affect more than 1 in every 10 people)*
- diarrhoea
- headache
- tiredness, lack of energy
- muscle pain
- itching, rash
- nausea
- abdominal pain
- constipation
- vomiting
- hair loss
- musculoskeletal pain, muscle pain, pain in extremity, pain in joints, bone pain and spinal pain upon discontinuing treatment with Nilotinib DRL
- slowing of growth in children and adolescents

Some side effects are common *(may affect up to 1 in 10 people)*
- upper respiratory tract infections
- stomach discomfort after meals, flatulence, swelling or bloating of the abdomen
- bone pain, pain in joints, muscle spasms, muscle weakness
- pain including back pain, neck pain and pain in extremity, pain or discomfort in the side of the body
- dry skin, acne, wart, decreased skin sensitivity, hives
- loss of appetite, disturbed sense of taste, weight decrease or increase
- insomnia, depression, anxiety
- night sweats, excessive sweating
- generally feeling unwell
- voice disorder
- nose bleed
- frequent urine output

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) or haemoglobin
- increase in the number of platelets or white cells, or specific types of white cells (eosinophils) in the blood
- high blood level of lipase or amylase (pancreas function)
- high blood level of bilirubin or liver enzymes (liver function)
- high blood level of creatinine or urea (kidney function)
- low or high blood level of insulin (a hormone regulating blood sugar level)
- low or high level of sugar, or high level of fats (including cholesterol) in the blood.
- high blood level of parathyroid hormone (a hormone regulating calcium and phosphorus level)
- change in blood proteins (low level of globulins or presence of paraprotein)
- high blood levels of enzymes (alkaline phosphatase, lactate dehydrogenase or creatine phosphokinase)
- high blood level of potassium, calcium, phosphorus or uric acid
- low blood level of magnesium, potassium, sodium, calcium, or phosphorus

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Nilotinib DRL

Storage
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Do not store above 30ºC. Store in the original package. Protect from moisture
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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

Nilotinib DRL is supplied as hard capsules.

Nilotinib DRL 150 mg hard capsules

White to yellowish powder in red opaque hard HPMC[1] capsules, size 1 with black horizontal imprint “150mg” on body

Nilotinib DRL 200 mg hard capsules

White to yellowish powder in light yellow opaque hard HPMC[1] capsules, size 0 with black horizontal imprint “200mg” on body

Pack size

PVC/PE/PVdC blisters or Aluminium-OPA/Alu/PVC blisters.

Ingredients

Active ingredient
- The active substance is nilotinib. Each hard capsule contains nilotinib (as hydrochloride dihydrate).

Inactive ingredients

Capsule Content:
Lactose Monohydrate, Crospovidone, Colloidal Anhydrous Silica, Magnesium Stearate

Capsule Shell:
Nilotinib DRL 150 mg hard capsules
Hypromellose, Purified Water, Carrageenan, Potassium Chloride, Erythrosine, Iron Oxide Yellow, Iron Oxide Red & Titanium Dioxide
Nilotinib DRL 200 mg hard capsules
Hypromellose, Purified Water, Carrageenan, Potassium Chloride, Iron Oxide Yellow & Titanium Dioxide

Printing Ink:
Shellac, Ethanol anhydrous, Isopropyl Alcohol, Butanol, Propylene Glycol, Purified water, Ammonia, Potassium Hydroxide & Black iron oxide.

MAL Number

xxxxxxxxx

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Product Registration Holder

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Date of Revision

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04/02/2026

Serial Number
NPRA (R2) 25/148