Package leaflet: Information for the user

Nilotinib Olpha 150 mg hard capsules
Nilotinib Olpha 200 mg hard capsules
nilotinib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Nilotinib Olpha is and what it is used for

What Nilotinib Olpha is
Nilotinib Olpha is a medicine containing an active substance called nilotinib.

What Nilotinib Olpha is used for
Nilotinib Olpha 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 Olpha 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 Olpha 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 Olpha blocks this signal, and thus stops the production of these cells.

Monitoring during Nilotinib Olpha 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 the body to see how Nilotinib Olpha is tolerated.
- pancreas and liver function in the body to see how Nilotinib Olpha 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 Olpha. If you are told to discontinue this medicine, your doctor will continue to monitor your CML and may tell you to re-start Nilotinib Olpha if your condition indicates that this is necessary.

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

2. What you need to know before you take Nilotinib Olpha

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

Do not take Nilotinib Olpha
- if you are allergic to nilotinib or any of the other ingredients of this medicine (listed in section 6).

If you think you may be allergic, tell your doctor **before taking Nilotinib Olpha**.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nilotinib Olpha:
- if you have suffered prior cardiovascular 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 lower your blood cholesterol (statins), or affect the heartbeat (anti-arrhythmics) or the liver (see Other medicines and Nilotinib Olpha).
- 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 Olpha 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.

<u>During treatment with Nilotinib Olpha</u>
- 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 Olpha.
- 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 Olpha.
- 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 Olpha. Your doctor should assess the level of fats (lipids) and sugar in your blood before initiating treatment with Nilotinib Olpha 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 Olpha.

If you are the parent of a child who is being treated with Nilotinib Olpha, tell the doctor if any of the above conditions apply to your child.

Children and adolescents
Nilotinib Olpha 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 Olpha 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.

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

Other medicines and Nilotinib Olpha
Nilotinib Olpha 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:
- anti-arrhythmics – used to treat irregular heart beat;
- chloroquine, halofantrine, clarithromycin, haloperidol, methadone, moxifloxacin – 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 dementia;
- 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 Olpha. If you are taking any of these, your doctor might prescribe other alternative medicines.

If you are taking a statin (a type of medicine to lower your blood cholesterol), talk to your doctor or pharmacist. If used with certain statins, Nilotinib Olpha may increase the risk of statin-related muscle problems, which on rare occasions can lead to serious muscle breakdown (rhabdomyolysis) resulting in kidney damage.

In addition, tell your doctor or pharmacist before taking Nilotinib Olpha if you are taking any antacids, which are medicines against heartburn. These medicines need to be taken separately from Nilotinib Olpha:
- 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 Olpha;
- 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 Olpha.

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

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

Pregnancy and breast-feeding
- **Nilotinib Olpha 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 Olpha 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.

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 Olpha 150 mg hard capsules and 200 mg hard capsules contain 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.

Nilotinib Olpha 150 mg hard capsules contains Allura Red AC
This medicine contains Allura Red AC, which may cause allergic reactions.

Nilotinib Olpha 200 mg hard capsules contains tartrazine
This medicine contains tartrazine, which may cause allergic reactions.

3. How to take Nilotinib Olpha

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 Nilotinib Olpha to take

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

When to take Nilotinib Olpha
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 Olpha at the same time each day will help you remember when to take your hard capsules.

How to take Nilotinib Olpha
- Swallow the hard capsules whole with water.
- Do not take any food together with the hard capsules.
- Do not open the hard capsules. If you or your child cannot swallow a whole capsule, other medicines containing nilotinib should be used instead of Nilotinib Olpha capsules.

How long to take Nilotinib Olpha
Continue taking Nilotinib Olpha 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.
Your doctor may consider discontinuing your treatment with Nilotinib Olpha based on specific criteria.
If you have questions about how long to take Nilotinib Olpha, talk to your doctor.

If you take more Nilotinib Olpha than you should
If you have taken more Nilotinib Olpha 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 hard capsules and this package leaflet. Medical treatment may be necessary.

If you forget to take Nilotinib Olpha
If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for a forgotten hard capsule.

If you stop taking Nilotinib Olpha
Do not stop taking this medicine unless your doctor tells you to do so. Stopping Nilotinib Olpha 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 Olpha.

If your doctor recommends that you discontinue treatment with Nilotinib Olpha
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 Nilotinib Olpha, your doctor will continue to carefully monitor your CML before, during and after you have discontinued Nilotinib Olpha and may tell you to re-start Nilotinib Olpha 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.

4. Possible 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.
- signs of musculoskeletal pain: pain in joints and muscles

- signs of heart disorders: 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 artery blockage: 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 temperature (coolness) of the affected leg, arm, toes or fingers
- signs of underactive thyroid gland: weight gain, tiredness, hair loss, muscle weakness, feeling cold
- signs of overactive thyroid gland: fast heartbeat, bulging eyes, weight loss, swelling at the front of the neck
- signs of kidney or urinary tract 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 high blood level of sugar: excessive thirst, high urine output, increased appetite with weight loss, tiredness
- signs of vertigo: dizziness or spinning sensation
- signs of pancreatitis: severe upper (middle or left) abdominal pain
- signs of skin disorders: painful red lumps, skin pain, skin reddening, peeling or blisters
- signs of water retention: rapid weight gain, swelling of hands, ankles, feet or face
- signs of migraine: severe headache often accompanied by nausea, vomiting and sensitivity to light
- signs of blood disorders: fever, easy bruising or unexplained bleeding, severe or frequent infections, unexplained weakness
- signs of clotting within a vein: swelling and pain in one part of the body
- signs of nervous system 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 lung disorders: difficulty breathing or painful breathing, cough, wheezing with or without fever, swelling of the feet or legs
- signs of gastrointestinal disorders: abdominal pain, nausea, vomiting of blood, black or bloody stools, constipation, heartburn, stomach acid reflux, swollen abdomen
- signs of liver disorders: yellow skin and eyes, nausea, loss of appetite, dark-coloured urine
- signs of liver infection: recurrence (reactivation of hepatitis B infection)
- signs of eye 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 electrolyte imbalance: 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)

Contact your doctor immediately if you notice any of the above side effects.

Some side effects are very common (may affect more than 1 in 10 people)
- diarrhoea
- headache
- lack of energy
- muscle pain
- itching, rash
- nausea
- constipation
- vomiting
- hair loss
- pain in limbs, bone pain and spinal pain on discontinuing treatment with Nilotinib Olpha
- slowing of growth in children and adolescents
- upper respiratory tract infection including sore throat and runny or stuffy nose, sneezing
- low level of blood cells (red cells, platelets) or haemoglobin
- high blood level of lipase (pancreas function)
- high blood level of bilirubin (liver function)

- high blood level of alanine aminotransferases (liver enzymes)

Some side effects are common (may affect up to 1 in 10 people)
- pneumonia
- abdominal pain, stomach discomfort after meals, flatulence, swelling or bloating of the abdomen
- bone pain, muscle spasms
- pain (including neck pain)
- dry skin, acne, decreased skin sensitivity
- weight decrease or increase
- insomnia, depression, anxiety
- night sweats, excessive sweating
- generally feeling unwell
- nose bleed
- signs of gout: painful and swollen joints
- inability to achieve or maintain an erection
- flu-like symptoms
- sore throat
- bronchitis
- ear pain, hearing noises (e.g., ringing, humming) in the ears that have no external source (also called tinnitus)
- haemorrhoids
- heavy periods
- itching at the hair follicles
- oral or vaginal thrush
- signs of conjunctivitis: discharge from the eye with itching, redness and swelling
- eye irritation, red eyes
- signs of hypertension: high blood pressure, headache, dizziness
- flushing
- signs of peripheral arterial occlusive disease: 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 temperature (coolness) of the legs or arms (possible signs of a blocked artery in the affected leg, arm, toes or fingers)
- shortness of breath (also called dyspnoea)
- mouth sores with gum inflammation (also called stomatitis)
- high blood level of amylase (pancreas function)
- high blood level of creatinine (kidney function)
- high blood level of alkaline phosphatase or creatine phosphokinase
- high blood level of aspartate aminotransferases (liver enzymes)
- high blood level of gamma glutamyltransferases (liver enzymes)
- signs of leukopenia or neutropenia: low level of white blood cells
- increase in the number of platelets or white cells in the blood
- low blood level of magnesium, potassium, sodium, calcium or phosphorus
- increased blood level of potassium, calcium or phosphorus
- high blood level of fats (including cholesterol)
- high blood level of uric acid

Some side effects are uncommon (may affect up to 1 in 100 people)
- allergy (hypersensitivity to Nilotinib Olpha)
- dry mouth
- breast pain
- pain or discomfort on the side of the body
- increased appetite
- breast enlargement in men
- herpes virus infection
- muscle and joint stiffness, joint swelling
- feeling body temperature change (including feeling hot, feeling cold)
- disturbed sense of taste

- frequent urine output
- signs of inflammation of the stomach lining: abdominal pain, nausea, vomiting, diarrhoea, bloating of the abdomen
- memory loss
- skin cyst, thinning or thickening of the skin, thickening of the outermost layer of the skin, skin discolouration
- signs of psoriasis: thickened patches of red/silver skin
- increased sensitivity of the skin to light
- difficulty hearing
- joint inflammation
- urinary incontinence
- inflammation of the intestine (also called enterocolitis)
- anal abscess
- nipple swelling
- symptoms of restless legs syndrome (an irresistable urge to move a part of the body, usually the leg, accompanied by uncomfortable sensations)
- signs of sepsis: fever, chest pain, elevated/increased heart rate, shortness of breath or rapid breathing
- skin infection (subcutaneous abscess)
- skin wart
- increase in specific types of white blood cells (called eosinophils)
- signs of lymphopenia: low level of white blood cells
- high blood level of parathyroid hormone (a hormone regulating calcium and phosphorus levels)
- high blood level of lactate dehydrogenase (an enzyme)
- signs of low blood level of sugar: nausea, sweating, weakness, dizziness, trembling, headache
- dehydration
- abnormal blood level of fat
- involuntary shaking (also called tremor)
- difficulty concentrating
- unpleasant and abnormal feeling when touched (also called dysaesthesia)
- tiredness (also called fatigue)
- sensation of numbness or tingling in the fingers and toes (also called peripheral neuropathy)
- paralysis of any muscle of the face
- red patch in the white of the eye caused by broken blood vessels (also called conjunctival haemorrhage
- blood in eyes (also called eye haemorrhage)
- eye irritation
- signs of heart attack (also called myocardial infarction): sudden and crushing chest pain, tiredness, irregular heartbeat
- signs of heart murmur: tiredness, chest discomfort, light-headedness, chest pain, palpitations
- fungal infection of the feet
- signs of heart failure: breathlessness, difficulty breathing when lying down, swelling of the feet or legs
- pain behind the breast bone (also called pericarditis)
- signs of hypertensive crisis: severe headache, dizziness, nausea
- leg pain and weakness brought on by walking (also called intermittent claudication)
- signs of narrowing of the arteries of the limbs: possible high blood pressure, painful cramping in one or both hips, thighs or calf muscles after certain activities such as walking or climbing stairs, leg numbness or weakness
- bruising (when you have not hurt yourself)
- fatty deposits in the arteries that can cause blockage (also called arteriosclerosis)
- signs of low blood pressure (also called hypotension): light-headedness, dizziness or fainting
- signs of pulmonary oedema: breathlessness
- signs of pleural effusion: fluid collection between the layers of tissue that line the lungs and chest cavity (which, if severe, can decrease the heart’s ability to pump blood), chest pain, cough, hiccups, rapid breathing
- signs of interstitial lung disease: cough, difficulty breathing, painful breathing

- signs of pleuritic pain: chest pain
- signs of pleurisy: cough, painful breathing
- hoarse voice
- signs of pulmonary hypertension: high blood pressure in the arteries of the lungs
- wheezing
- sensitive teeth
- signs of inflammation (also called gingivitis): gum bleeding, tender or enlarged gums
- high blood level of urea (kidney function)
- change in blood proteins (low level of globulins or presence of paraprotein)
- high blood level of unconjugated bilirubin
- high blood level of troponins

Some side effects are rare (may affect up to 1 in 1,000 people)
- reddening and/or swelling and possibly peeling on the palms of the hands and soles of the feet (so-called hand-foot syndrome)
- warts in the mouth
- feeling of hardening or stiffness in the breasts
- inflammation of the thyroid gland (also called thyroiditis)
- disturbed or depressed mood
- signs of secondary hyperparathyroidism: bone and joint pain, excessive urination, abdominal pain, weakness, tiredness
- signs of narrowing of the arteries in the brain: loss of vision in part or all of both eyes, double vision, vertigo (spinning sensation), numbness or tingling, loss of coordination, dizziness or confusion
- swelling of the brain (possible headache and/or mental status changes)
- signs of optic neuritis: blurred vision, loss of vision
- signs of heart dysfunction (ejection fraction decreased): tiredness, chest discomfort, lightheadedness, pain, palpitations
- low or high blood level of insulin (a hormone regulating blood sugar level)
- low blood level of insulin C peptide (pancreas function)
- sudden death

The following other side effects have been reported with frequency not known (cannot be estimated from the available data):
- signs of heart dysfunction (ventricular dysfunction): shortness of breath, exertion at rest, irregular heartbeat, chest discomfort, light-headedness, pain, palpitations, excessive urination, swelling in the feet, ankles and abdomen.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nilotinib Olpha

- 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 after EXP. The expiry date refers to the last day of that month.
- Do not store above 30 °C.
- Store in the original package in order to protect from moisture.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- 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.

6. Contents of the pack and other information

What Nilotinib Olpha contains
- The active substance is nilotinib.

Nilotinib Olpha 150 mg hard capsules
- Each hard capsule contains nilotinib hydrochloride monohydrate equivalent to 150 mg nilotinib.
  The other ingredients are:
  Capsule content: lactose (as monohydrate), crospovidone, poloxamer, silica colloidal anhydrous, magnesium stearate.
  Capsule shell: gelatin, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), Allura Red AC – FD&C Red 40 (E129).
  Printing ink: shellac (E904), black iron oxide (E172), propylene glycol, potassium hydroxide.

Nilotinib Olpha 200 mg hard capsules
- Each hard capsule contains nilotinib hydrochloride monohydrate equivalent to 200 mg nilotinib.
  The other ingredients are:
  Capsule content: lactose (as monohydrate), crospovidone, poloxamer, silica colloidal anhydrous, magnesium stearate.
  Capsule shell: gelatin, titanium dioxide (E171), tartrazine – FD&C Yellow 5 (E102).
  Printing ink: shellac (E904), black iron oxide (E172), propylene glycol, potassium hydroxide.

What Nilotinib Olpha looks like and contents of the pack

Nilotinib Olpha 150 mg hard capsules
Nilotinib Olpha 150 mg is supplied as hard gelatine capsules (approx. length: 19 mm) with orange cap, imprinted with “NLT150” in black ink and orange body, containing an off-white to yellow powder.

Nilotinib Olpha 150 mg hard capsules are available in unit packs containing 28 hard capsules and in multipacks of 112 hard capsules (4 packs of 28 hard capsules).

Nilotinib Olpha 200 mg hard capsules
Nilotinib Olpha 200 mg is supplied as hard gelatine capsules (approx. length: 22 mm) with ivory cap, imprinted with “NLT200” in black ink and ivory body, containing an off-white to yellow powder.

Nilotinib Olpha 200 mg hard capsules are available in unit packs containing 28 hard capsules and in multipacks of 112 hard capsules (4 packs of 28 hard capsules).

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Olpha AS,
Rupnicu iela 5,
Olaine, Olaines novads, LV-2114,
Latvia

Manufacturer
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Bluepharma - Indústria Farmacêutica, S.A.
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria:	Nilotinib Olpha 150 mg, 200 mg hartkapseln
Belgium:	Nilotinib Olpha 150 mg, 200 mg gélules; Nilotinib Olpha 150 mg, 200 mg harde capsules; Nilotinib Olpha 150 mg, 200 mg Hartkapseln
Bulgaria:	Нилотиниб Олфа 150 мг., 200 мг. твърди капсули
Croatia:	Nilotinib Olpha 150 mg, 200 mg tvrde kapsule
Cyprus:	Nilotinib Olpha 150 mg, 200 mg hard capsules
Czechia:	Nilotinib Olpha
Denmark:	Nilotinib Olpha
Estonia:	Nilotinib Olpha
Finland:	Nilotinib Olpha 150 mg, 200 mg kapseli, kova
France:	Nilotinib Olpha 150 mg, 200 mg, gélule
Germany:	Nilotinib Olpha 150 mg, 200 mg hartkapseln
Greece:	Nilotinib / Olpha
Hungary:	Nilotinib Olpha 150 mg, 200 mg kemény kapszula
Ireland:	Nilotinib Olpha 150 mg, 200 mg hard capsules
Italy:	Nilotinib Olpha
Latvia:	Nilotinib Olpha 150 mg, 200 mg cietās kapsulas
Lithuania:	Nilotinib Olpha 150 mg, 200 mg kietosios kapsulės
Luxembourg:	Nilotinib Olpha 150 mg, 200 mg hard capsules
Malta:	Nilotinib Olpha 150 mg, 200 mg hard capsules
Netherlands:	Nilotinib Olpha 150 mg, 200 mg harde capsules
Norway:	Nilotinib Olpha
Poland:	Nilotinib Olpha
Portugal:	Nilotinib Olpha 150 mg, 200 mg cápsulas
Romania:	Nilotinib Olpha 150 mg, 200 mg capsule
Slovakia:	Nilotinib Olpha 150 mg, 200 mg tvrdé kapsuly
Slovenia:	Nilotinib Olpha 150 mg, 200 mg trde kapsule
Spain:	Nilotinib Olpha 150 mg, 200 mg cápsulas duras
Sweden:	Nilotinib Olpha 150 mg, 200 mg hårda kapslar

This leaflet was last revised in