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## **Nilotinib**

pronounced as (nye loe' ti nib)

### **IMPORTANT WARNING:**

Nilotinib may cause QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death). Tell your doctor if you or anyone in your family has or has ever had long QT syndrome (an inherited condition in which a person is more likely to have QT prolongation) or you have or have ever had low levels of potassium or magnesium in your blood, an irregular heartbeat, or liver disease. Tell your doctor and pharmacist if you are taking amiodarone (Nexterone, Pacerone); antifungals such as ketoconazole, itraconazole (Sporanox, Tolsura), or voriconazole (Vfend); chloroquine (Plaquenil); clarithromycin; disopyramide (Norpace); erythromycin (E.E.S., Eryc, PCE); certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); haloperidol (Haldol); methadone (Dolophine, Methadose); moxifloxacin; nefazodone; pimozide (Orap); procainamide; quinidine (in Nuedexta); sotalol (Betapace, Betapace AF, others); and thioridazine. If you experience any of the following symptoms, stop taking nilotinib and call your doctor immediately: fast, pounding, or irregular heartbeat; fainting; loss of consciousness; or seizures.

Do not eat any food for at least 2 hours before taking nilotinib and for 1 hour after taking this medication.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests, such as blood tests and electrocardiograms (EKGs, tests that record the electrical activity of the heart) before and during your treatment to be sure that it is safe for you to take nilotinib.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with nilotinib and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking nilotinib.

## Why is this medication prescribed?

Nilotinib is used to treat certain types of chronic myeloid leukemia (CML; a type of cancer of the white blood cells) who have recently found to have this condition in adults and children 1 year of age and older. It is also used to treat certain types of CML in adults whose disease could not be treated successfully with imatinib (Gleevec) or adults who cannot take imatinib because of side effects. Nilotinib is also used to treat certain types of CML in children 1 year of age or older whose disease could not be treated successfully with other tyrosine kinase inhibitor therapies or who cannot take these medications because of side effects. Nilotinib is in a class of medications called kinase inhibitors. It works by blocking the action of the abnormal protein that signals cancer cells to multiply. This helps to stop or slow the spread of cancer cells.

## How should this medicine be used?

Nilotinib comes as a capsule to take by mouth. It is usually taken without food twice a day. Nilotinib should be taken on an empty stomach, at least 2 hours before or 1 hour after eating any food. Take nilotinib at around the same times every day. Try to space your doses about 12 hours apart. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take nilotinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with a glass of water; do not split, chew, or crush them. If you are not able to swallow the capsules whole, mix the contents of a capsule in one teaspoon of applesauce. Swallow the mixture immediately (within 15 minutes.) Do not store the mixture for future use.

Your doctor may decrease your nilotinib dose or stop your treatment depending on how well the medication works for you and if you experience any side effects. Continue to take nilotinib even if you feel well. Do not stop taking nilotinib without talking to your doctor.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking nilotinib,

- tell your doctor and pharmacist if you are allergic to nilotinib, any other medications, or any of the ingredients in nilotinib capsules. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: certain cholesterol-lowering medications (statins) including atorvastatin (Lipitor, in Caduet), fluvastatin (Lescol XL), lovastatin (Altoprev), and simvastatin (Flolipid, Zocor, in Vytorin); proton-pump inhibitors such as esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), and rabeprazole (AcipHex); and rifampin (Rifadin). Your doctor may need to change the doses of your medications or

monitor you carefully for side effects. Many other medications may also interact with nilotinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

- if you are taking antacids containing magnesium, aluminum (Maalox, Mylanta, Tums, others), or simethicone, take the antacid 2 hours before or at least 2 hours after you take nilotinib.
- if you are taking a medication for indigestion, heartburn, or ulcers such as cimetidine (Tagamet), famotidine (Pepcid, in Duexis), nizatidine (Axicid), or ranitidine (Zantac), take it at least 10 hours before or at least 2 hours after you take nilotinib.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have had a stroke or surgery to remove the entire stomach (total gastrectomy). Also, tell your doctor if you have or have ever had decreased blood flow to your legs, any heart problems, bleeding problems, liver problems, pancreatitis (swelling of the pancreas, a gland behind the that produces substances to help with digestion), or any condition that makes it difficult for you to digest lactose (milk sugar) or other sugars.
- tell your doctor if you are pregnant or plan to become pregnant. You should not become pregnant while you are taking nilotinib. You should use effective birth control to prevent pregnancy during your treatment with nilotinib and for 14 days after your final dose. Talk to your doctor about birth control methods that you can use during your treatment. If you become pregnant while taking nilotinib, call your doctor immediately. Nilotinib may harm the fetus.
- tell your doctor if you are breast-feeding. You should not breast-feed while you are taking nilotinib and for 14 days after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking nilotinib.

## What special dietary instructions should I follow?

Do not eat grapefruit, drink grapefruit juice, or take any supplement containing grapefruit extract while taking this medication.

## What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Nilotinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- rash
- itching
- nausea
- vomiting
- diarrhea
- constipation

- heartburn
- gas
- loss of appetite
- headache
- dizziness
- tiredness
- difficulty falling asleep or staying asleep
- night sweats
- muscle cramps
- back, bone, joint, limb, or muscle pain
- hair loss
- dry or reddened skin
- numbness, burning, or tingling in the hands or feet

**Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:**

- unusual bleeding or bruising
- blood in urine
- bloody or black, tarry stools
- sudden headache, confusion, or changes in vision
- unusual tiredness or weakness
- chest pain or discomfort
- problems walking or speaking
- numbness
- change in leg skin color
- pain or cold sensation in legs
- stomach pain with nausea and vomiting
- fever, chills, sore throat, ongoing cough and congestion, or other signs of infection
- pale skin
- shortness of breath
- weight gain
- swelling of hands, ankles, feet, or face
- pain or discomfort in the right upper stomach area
- yellowing of the skin and eyes

- dark urine
- urinating less often than usual

Nilotinib may cause children to grow more slowly. Your child's doctor will watch your child's growth carefully while your child is taking nilotinib. Talk to your child's doctor about the risks of giving this medication to your child.

Nilotinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [http://www.upandaway.org]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [http://goo.gl/c4Rm4p]) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [https://www.poisonhelp.org/help]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- fever, sore throat, chills, or other signs of infection
- vomiting
- drowsiness

## What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Tasigna®

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