



Nilotinib

(nil ot' i nib)

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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 (Cordarone, Pacerone); antifungals such as ketoconazole (Nizoral), itraconazole (Sporanox), or voriconazole (Vfend); cisapride (Propulsid); clarithromycin (Biaxin, in Prevpac); disopyramide (Norpace); dofetilide (Tikosyn); erythromycin (E.E.S., E-Mycin, Erythrocin); certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); moxifloxacin (Avelox); nefazodone; pimozone (Orap); procainamide (Procanbid, Pronestyl); quinidine; sotalol (Betapace, Betapace AF); telithromycin (Ketek); 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.

Take nilotinib on an empty stomach, at least 1 hour before or 2 hours after eating any food.

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>) 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 leukemia (cancer that begins in the white blood cells) in people whose disease could not be treated successfully with imatinib (Gleevec) or people who cannot take imatinib. 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 1 hour before or 2 hours 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.

Your doctor may decrease your dose of nilotinib during your treatment. This will depend on how well the medication works for you and any side effects you may experience. 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 or any other medications.
- 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 angiotensin-receptor blockers such as irbesartan (Avapro) and losartan (Cozaar, in Hyzaar); anticoagulants ("blood thinners") such as warfarin (Coumadin); aripiprazole (Abilify); certain benzodiazepines such as alprazolam (Xanax), diazepam (Valium), midazolam, and triazolam (Halcion); buspirone (Buspar); certain calcium channel blockers such as amlodipine (Norvasc), diltiazem (Cardizem, Dilacor, Tiazac, others), felodipine (Plendil), nicardipine (Cardene), nifedipine (Adalat, Procardia), nisoldipine (Sular), and verapamil (Calan, Isoptin, Verelan); certain cholesterol-lowering medications (statins) including atorvastatin (Lipitor), fluvastatin (Lescol), lovastatin (Mevacor), and simvastatin (Zocor); chlorpheniramine (Chlor-Trimeton, other cough and cold products); dexamethasone (Mymethasone); flecainide (Tambocor); haloperidol (Haldol); certain medications for depression such as amitriptyline, desipramine (Norpramin), duloxetine (Cymbalta), imipramine (Tofranil), paroxetine (Paxil), and venlafaxine (Effexor); certain oral medications for diabetes such as glipizide (Glucotrol) and tolbutamide; certain medications that suppress the immune system such as cyclosporine (Neoral, Sandimmune) and tacrolimus (Prograf); certain medications for seizures such as carbamazepine (Equetro, Carbatrol, Tegretol), phenobarbital, and phenytoin (Dilantin, Phenytek); methadone (Methadose); mexiletine; certain nonsteroidal anti-inflammatory drugs (NSAIDs) such as celecoxib (Celebrex), diclofenac (Voltaren), ibuprofen (Advil, Motrin), naproxen (Aleve, Naprosyn), and piroxicam (Feldene); ondansetron (Zofran); propafenone (Rythmol); quinine (Qualaquin); rifabutin (Mycobutin); rifampin (Rifadin); rifapentine (Priftin); risperidone (Risperdal); sildenafil (Viagra, Revatio); tamoxifen; testosterone (Androderm, Androgel, Striant, others); timolol; torsemide; tramadol (Ultram, in Ultracet); trazodone; and vincristine. 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.

- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had any heart problems, pancreatitis (swelling of the pancreas, a gland behind the stomach 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. 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.
- 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:

- unexplained bleeding or bruising
- blood in urine or stool
- unexplained weakness

- fever, sore throat, chills, or other signs of infection
- shortness of breath
- swelling of hands, ankles, feet, or face
- sudden stomach area pain
- yellowing of the skin and eyes

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

What storage conditions are needed for this medicine?

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). Throw away any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

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

- Tassigna®

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