

PATIENT & CAREGIVER EDUCATION

Nilotinib

This information from Lexicomp[®] explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Danziten; Tasigna

Brand Names: Canada

APO-Nilotinib; REDDY-Nilotinib; Tasigna

Warning

- This drug may cause a prolonged QT interval (a type of heartbeat that is not normal). If this happens, the chance of other unsafe and sometimes deadly abnormal heartbeats may be raised. Sudden deaths have happened in people taking this drug. Do not give this drug if your child has low potassium or magnesium levels or has ever had a long QT on ECG. Your child's heartbeat will be watched often with an ECG. If you have questions, talk with your child's doctor.
- Do not give this drug if your child is taking any drugs that can raise the risk of a prolonged QT interval (a type of abnormal heartbeat). There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.
- Give this drug on an empty stomach. Do not let your child eat for at least 2 hours before and 1 hour after taking this drug.

What is this drug used for?

- It is used to treat a type of leukemia.
- It may be given to your child for other reasons. Talk with

the doctor.

Tablets:

- This form of this drug is not approved for use in children. However, your child's doctor may decide the benefits of taking this drug outweigh the risks. If your child has been given this form of this drug, ask your child's doctor for information about the benefits and risks. Talk with your child's doctor if you have questions about this drug.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child is taking another drug that has the same drug in it.
- If you have been told that your child's body has problems with certain sugars (lactose, glucose, galactose). Some products have lactose.
- If your child takes any drugs (prescription or OTC, natural products, vitamins) that must not be taken with this drug, like some other drugs used for HIV or certain drugs used for seizures, infection, or stomach or bowel problems. There are many drugs that must not be taken

with this drug.

If your child is breast-feeding a baby:

- Be sure your child does not breast-feed a baby while taking this drug and for 2 weeks after the last dose.

This is not a list of all drugs or health problems that interact with this drug.

Tell the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have your child's blood work checked and an ECG (to see how your child's heart beats) as you have been told by the doctor.
- If your child has high blood sugar (diabetes), talk with the doctor. This drug can raise blood sugar.

- This drug may lower the ability of the bone marrow to make blood cells that the body needs. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. If you have questions, talk with the doctor.
- Your child may have more chance of getting infections. Have your child wash hands often. Avoid crowds and people with infections, colds, or flu.
- Your child may bleed more easily. Make sure your child is careful and avoids injury. Be sure your child has a soft toothbrush. Rarely, some bleeding problems have been deadly.
- Talk with the doctor before your child gets any vaccines. Use of some vaccines with this drug may either raise the chance of very bad infection or make the vaccine not work as well.
- Avoid giving your child grapefruit and grapefruit juice.
- High cholesterol and triglyceride levels have happened with this drug. If your child has high cholesterol or triglycerides, talk with the doctor.
- There are different brands and forms (capsules and tablets) of this drug. Do not switch between different brands or forms of this drug without talking to the doctor who ordered it.

- If your child is in remission and your child's doctor tells you to stop giving this drug, your child may have more muscle and bone signs than before treatment was stopped. These signs include arm, leg, bone, spine, muscle, or joint pain. If you have questions, talk with your child's doctor.
- This drug may affect growth in children and teens in some cases. They may need regular growth checks. Talk with the doctor.
- As your child grows, your child's doctor may change your child's dose. Give this drug as your child's doctor has told you.
- If your child is of childbearing age, a pregnancy test will need to be done before starting this drug to make sure your child is not pregnant.

If your child is or may be sexually active:

- This drug may cause harm to the unborn baby if your child takes it during pregnancy.
- If your child may become pregnant, have your child use birth control while taking this drug. Your child will also need to use birth control for 2 weeks after the last dose unless you have been told otherwise. Be sure you know how long your child needs to use birth control. If your child gets pregnant, call the doctor right away.

- If your child's sex partner may get pregnant, they may need to use birth control while your child takes this drug and for some time after the last dose. Talk with the doctor to see if your child needs to use birth control while taking this drug.

What are some side effects that I need to call my child's doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your child's doctor or get medical help right away if your child has any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine;

black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.

- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of electrolyte problems like mood changes; confusion; muscle pain, cramps, or spasms; weakness; shakiness; change in balance; an abnormal heartbeat; seizures; loss of appetite; or severe upset stomach or throwing up.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Chest pain or pressure, a fast heartbeat, or an abnormal heartbeat.
- Dizziness or passing out.
- This drug may cause your child to swell or keep fluid in the body. Tell your child's doctor if swelling, weight gain,

or trouble breathing happens after this drug is given.

- People with a certain type of leukemia taking this drug may have lower blood flow to the heart, brain, or leg. Call the doctor right away if your child has chest pain, numbness or weakness, trouble walking or speaking, leg pain, leg feels cold, or change in skin color of the leg.
- Patients with cancer who take this drug may be at greater risk of getting a severe health problem called tumor lysis syndrome (TLS). This may lead to death. Call your child's doctor right away if your child has a fast or abnormal heartbeat; any passing out; trouble passing urine; muscle weakness or cramps; upset stomach, throwing up, diarrhea, or not able to eat; or feels sluggish.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Hair loss.
- Headache.
- Feeling tired or weak.

- Back, muscle, or joint pain.
- Muscle spasm.
- Trouble sleeping.
- Signs of a common cold.
- Nose or throat irritation.
- Itching.
- Night sweats.
- Dry skin.
- Stomach pain.
- Decreased appetite.
- Constipation, diarrhea, throwing up, and upset stomach are common with this drug. If these happen, talk with your child's doctor about ways to lower these side effects. Call your child's doctor right away if any of these effects bother your child, do not go away, or are severe.

These are not all of the side effects that may occur. If you have questions about side effects, call your child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

- Give this drug on an empty stomach. Do not let your child eat for at least 2 hours before and 1 hour after taking this drug.
- Have your child swallow whole with a full glass of water.
- Do not let your child chew or crush.
- Some brands of this drug may be opened and the contents sprinkled on 1 teaspoon (5 mL) of applesauce. Some brands must not be opened. Be sure you know if your child's brand may be opened. If you sprinkle this drug on applesauce, have your child swallow within 15 minutes after mixing. Do not store for future use.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- Do not give cimetidine, famotidine, nizatidine, or ranitidine at the same time as this drug. Give this drug at least 2 hours before or 10 hours after your child takes these drugs.
- Do not give antacids within 2 hours before or 2 hours after giving this drug.

What do I do if my child misses a dose?

- Skip the missed dose and go back to your child's normal time.
- Do not give 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health

care provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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