

Medication Guide
DANZITEN (dan-zi-ten)
(nilotinib)
tablets

What is the most important information I should know about DANZITEN?

DANZITEN can cause a possible life-threatening heart problem called QTc prolongation. QTc prolongation causes an irregular heartbeat, which may lead to sudden death.

Your healthcare provider should check the electrical activity of your heart with a test called an electrocardiogram (ECG):

- before starting DANZITEN
- 7 days after starting DANZITEN
- with any dose changes
- regularly during DANZITEN treatment

You may lower your chances for having QTc prolongation with Nilotinib if you:

- Do not drink grapefruit juice, eat grapefruit, or take supplements containing grapefruit extract during treatment with DANZITEN.
Grapefruit products increase the amount of Nilotinib in your body.
- Avoid taking other medicines or supplements with Nilotinib that can also cause QTc prolongation.
- Nilotinib can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects.
- Do not take any other medicine during treatment with DANZITEN unless your healthcare provider tells you it is okay to do so.
- For more information, see “How should I take DANZITEN?”

Call your healthcare provider right away if you feel lightheaded, faint, or have an irregular heartbeat during treatment with DANZITEN. These can be symptoms of QTc prolongation.

See “**What are the possible side effects of DANZITEN?**” for more information about side effects.

What is DANZITEN?

DANZITEN is a prescription medicine used to treat:

- adults who have been newly diagnosed with a certain type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- adults with chronic phase Ph+ CML or accelerated phase Ph+ CML who:
 - o are no longer benefiting from other treatments, including imatinib (Gleevec), or
 - o have taken other treatments, including imatinib (Gleevec), and cannot tolerate them.

It is not known if nilotinib is safe and effective in children younger than 1 year of age with newly diagnosed, resistant, or intolerant Ph+ CML in chronic phase.

The long-term effects of treating children with nilotinib for a long period of time are not known.

Who should not take DANZITEN?

Do not take if you have:

- low levels of potassium or magnesium in your blood
- long QTc syndrome

Before taking DANZITEN, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have had a stroke or other problems due to decreased blood flow to the brain
- have problems with decreased blood flow to your legs
- have irregular heartbeat
- have QTc prolongation or a family history of it
- have liver problems
- have had pancreatitis
- have low blood levels of potassium or magnesium in your blood
- have bleeding problems
- had a surgical procedure involving the removal of the entire stomach (total gastrectomy)
- are pregnant or plan to become pregnant. Nilotinib can harm your unborn baby. Tell your healthcare provider right away if you are pregnant, or if you become pregnant during treatment with DANZITEN.

In females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with DANZITEN.

- Use effective birth control (contraception) during treatment with DANZITEN and for 14 days after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if Nilotinib passes into your breast milk. Do not breastfeed during treatment and for 14 days after your last dose of DANZITEN.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

If you need to take antacids (medicines to treat heartburn) do not take them at the same time that you take DANZITEN. If you take:

- **a medicine to block the amount of acid produced in the stomach (H2 blocker):** Take these medicines **about 10 hours before** you take DANZITEN, **or about 2 hours after** you take DANZITEN.
- **an antacid that contains aluminum hydroxide, magnesium hydroxide, and simethicone to reduce the amount of acid in the stomach:** Take these medicines **about 2 hours before or about 2 hours after** you take DANZITEN.

Nilotinib can interact with many medicines and supplements and increase your chance for serious and life-threatening side effects. **See “What is the most important information I should know about DANZITEN?”**

How should I take DANZITEN?

- Do not switch from DANZITEN to other medicines that contain nilotinib without talking to your healthcare provider. The amount of nilotinib in a dose of DANZITEN may not be the same as the amount in other medicines that contain nilotinib.
- Take DANZITEN exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking DANZITEN unless your healthcare provider tells you.
- DANZITEN is a long-term treatment.
- Take your prescribed dose of DANZITEN 2 times a day, about 12 hours apart.
- Swallow DANZITEN tablets whole with water. Do not cut, crush, or chew the tablets. If you cannot swallow DANZITEN whole, tell your healthcare provider.
- Take DANZITEN with or without food.
- Do not drink grapefruit juice, eat grapefruit, or take supplements containing grapefruit extract at any time during treatment. **See “What is the most important information I should know about DANZITEN?”**
- If you miss a dose, just take your next dose at your regular time. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much DANZITEN, call your healthcare provider or go to the nearest hospital emergency room right away. Symptoms may include vomiting and drowsiness.
- During treatment with DANZITEN your healthcare provider will do tests to check for side effects and to see how well DANZITEN is working for you. The tests will check your:
 - heart
 - blood cells (white blood cells, red blood cells, and platelets). Your blood cells should be checked every 2 weeks for the first 2 months and then monthly.
 - electrolytes (potassium, magnesium)
 - pancreas and liver function
 - bone marrow samples

Your healthcare provider may change your dose. Your healthcare provider may have you stop DANZITEN for some time or lower your dose if you have side effects with it.

- Your healthcare provider will monitor your CML during treatment with DANZITEN to see if you are in a remission. After at least 3 years of treatment with DANZITEN, your healthcare provider may do certain tests to determine if you continue to be in remission. Based on your test results, your healthcare provider may decide if you may be eligible to try stopping treatment with DANZITEN. This is called Treatment Free Remission (TFR).
- Your healthcare provider will carefully monitor your CML during and after you stop taking DANZITEN. Based on your test results, your healthcare provider may need to re-start your DANZITEN if your CML is no longer in remission.
- It is important that you are followed by your healthcare provider and undergo frequent monitoring to find out if you need to re-start your DANZITEN treatment because you are no longer in TFR. Follow your healthcare provider’s instructions about re-starting DANZITEN if you are no longer in TFR.

What are the possible side effects of DANZITEN?

DANZITEN may cause serious side effects, including:

- **See “What is the most important information I should know about DANZITEN?”**
- **Low blood cell counts.** Low blood cell counts (red blood cells, white blood cells, and platelets) are common with DANZITEN, but can also be severe. Your healthcare provider will check your blood counts regularly during treatment with DANZITEN. Call your healthcare provider or get medical help right away if you develop any signs or symptoms of low blood counts, including:

- fever
- chills or other signs of infection
- unexplained bleeding or bruising
- unexplained weakness
- shortness of breath

- **Decreased blood flow to the leg, heart, or brain.** People who have recently been diagnosed with Ph+ CML and take DANZITEN may develop decreased blood flow to the leg, the heart, or brain.

Get medical help right away if you suddenly develop any of the following symptoms:

- chest pain or discomfort
- numbness or weakness
- problems walking or speaking
- leg pain
- your leg feels cold
- change in the skin color of your leg

- **Pancreas inflammation (pancreatitis).** Tell your healthcare provider right away if you develop any symptoms of pancreatitis, including sudden stomach area pain with nausea and vomiting.
- **Liver problems.** DANZITEN can increase your risk of liver problems. People who have had liver problems in the past may be at risk for getting liver problems with DANZITEN. Call your healthcare provider or get medical help right away if you develop any symptoms of liver problems, including:
 - stomach area (abdominal) pain
 - yellow skin and eyes
 - dark-colored urine
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. Your healthcare provider may do blood tests to check you for TLS. TLS can cause you to have:
 - kidney failure and the need for dialysis treatment
 - an abnormal heartbeat
- **Bleeding problems.** Serious bleeding problems and death have happened during treatment with DANZITEN. Tell your healthcare provider right away if you develop any signs and symptoms of bleeding during treatment with DANZITEN.
- **Fluid retention.** Your body may hold too much fluid (fluid retention). Symptoms of fluid retention include shortness of breath, rapid weight gain, and swelling.
- **Abnormal growth or development in children.** Effects on growth and development have happened in children with chronic phase Ph+ CML during treatment with nilotinib. Some children and adolescents may have slower than normal growth during treatment with nilotinib.

The most common side effects of DANZITEN in adults include:

- nausea
- rash
- headache
- tiredness
- itching
- vomiting
- diarrhea
- cough
- constipation
- muscle and joint pain
- runny or stuffy nose, sneezing, sore throat
- fever
- night sweats

Side effects in adults attempting treatment free remission:

If you and your healthcare provider decide that you can stop taking DANZITEN and try treatment free remission (TFR), you may have more muscle and bone (musculoskeletal) symptoms than before you stopped treatment. Symptoms may include:

- muscle pain
- arm and leg pain
- joint pain
- bone pain
- spine pain

Tell your healthcare provider if you have any side effect that bothers you or does not go away. These are not all of the possible side effects of DANZITEN.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DANZITEN?

- Store DANZITEN at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.

Keep DANZITEN and all medicines out of the reach of children.

General information about the safe and effective use of DANZITEN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DANZITEN for a condition for which it was not prescribed. Do not give DANZITEN to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DANZITEN that is written for health professionals.

What are the ingredients in DANZITEN?

Active ingredient: nilotinib tartrate

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, iron oxide red (in 71 mg strength tablets), iron oxide yellow (in 95 mg strength tablets), magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Additional pediatric use information is approved for Novartis Pharmaceuticals Corporation's Tasigna® (nilotinib) capsules. However, due to Novartis Pharmaceuticals Corporation's marketing exclusivity rights, this drug product is not labeled with that pediatric information.

Manufactured for:
Azurity Pharmaceuticals, Inc.
Woburn, MA 0180

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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