

**Fast Start**

**FIRST MONTH FREE**  
ONE PER PATIENT PER LIFETIME\*

**ONE TIME ONLY**

*Manufacturer Paid, No Prior Authorization Required*

BIN# 610524	Group# 40028208
PCN# 1016	MEM ID# <b>1442209098</b>

Eligible patients may receive their **first month of Danziten® FREE**. This coupon is valid for one-time use only and cannot be copied.\*

 **Danziten®**  
(nilotinib) tablets 71mg, 95mg

**\*Subject to Terms and Conditions below**

Patients who have been prescribed Danziten® (nilotinib) tablets 71mg, 95mg may be eligible to receive **first month supply FREE**, which will allow them to start their treatment quickly. See below for Terms and Conditions of this program.

 **Danziten®**  
(nilotinib) tablets 71mg, 95mg

**First Free Month Offer Terms and Conditions**

- The patient must have a valid prescription for Danziten® (nilotinib).
- The patient must be 18 years of age or older to be eligible for this program.
- This offer is good for all eligible patients who are residents of the United States or Puerto Rico. Void where prohibited by law.
- Offer is limited to one per patient per lifetime and is not transferable. Not valid if reproduced.
- This first free month offer is not health insurance.
- No claim for reimbursement for product dispensed pursuant to this offer may be submitted to any third-party payer, whether a commercial, private or a government payer.
- This offer cannot be combined with any other rebate/offer, free trial or similar for the specified prescription.
- Valid only for patients new to Danziten® (nilotinib) and for their first month of medication. Existing and restart patients to Danziten® (nilotinib) are not eligible.

**Patient Instructions:**

This first free month offer is valid for up to a 30 days' supply of Danziten® (nilotinib). Offer must be presented to your pharmacist along with a valid prescription. Offer is valid for your first prescription of Danziten® (nilotinib) and one per patient per lifetime. Please call 1-800-657-7613 with any questions. Azurity and its service providers reserve the right to rescind, recall, revoke or amend this without notice at any time.

**Pharmacist Instructions:**

The first free month offer must accompany a valid prescription. Patient must be naïve to Danziten® (nilotinib). One offer per patient per lifetime and for patient's first month of medication. No substitution allowed. Please dispense at no cost to the patient. For reimbursement, please submit this electronically as a primary claim to BIN# 610524, RxPCN 1016, and RxGroup# 40028208. Do not submit to any other payer. For questions, please call the Help Desk at 1-800-657-7613. Azurity and its service providers reserve the right to rescind, recall, revoke or amend this without notice at any time.

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## IMPORTANT SAFETY INFORMATION

### DANZITEN® (nilotinib) tablets, for oral use

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:
  - Are no longer benefiting from other treatments, including imatinib (Gleevec), or
  - Have taken other treatments, including imatinib (Gleevec), and cannot tolerate them.

**WARNING: QT PROLONGATION and SUDDEN DEATHS**  
**See Full Prescribing Information for complete Boxed Warning.**

- Nilotinib prolongs the QT interval. Prior to DANZITEN administration and periodically, monitor for hypokalemia or hypomagnesemia and correct deficiencies. (5.3) Obtain ECGs to monitor the QTc at baseline, seven days after initiation, and periodically thereafter, and following any dose adjustments. (5.3, 5.4, 5.8, 5.12)
- Sudden deaths have been reported in patients receiving nilotinib. (5.4) Do not administer DANZITEN to patients with hypokalemia, hypomagnesemia, or long QT syndrome. (4, 5.3)
- Avoid use of concomitant drugs known to prolong the QT interval and strong CYP3A4 inhibitors. (7.1, 7.2)

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.

## ADDITIONAL IMPORTANT SAFETY INFORMATION

### Do not take DANZITEN if you have

- Low levels of potassium or magnesium in your blood
- Long QTc syndrome

### What are the possible side effects of DANZITEN?

DANZITEN can cause serious side effects, including

**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, unexplained bleeding or bruising, shortness of breath, chills or other signs of infection, and unexplained weakness.

**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, including chest pain or discomfort, problems walking or speaking, your leg feels cold, numbness or weakness, leg pain, and 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, and 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 or 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 include:

- Nausea
- Muscle and joint pain
- Cough
- Fever
- Tiredness
- Vomiting

- Rash
- Constipation
- Headache
- Runny or stuffy nose, sneezing, sore throat
- Itching
- Night sweats
- Diarrhea

### Side effects in adults attempting treatment-free remission (TFR):

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

- Muscle pain
- Arm and leg pain
- Bone pain
- Spine pain
- Joint pain

*These are not all the possible side effects of DANZITEN. Please see Full Prescribing Information for a full list.*

### Before taking DANZITEN, tell your doctor about all your medical conditions, including:

- 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.

**Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure. Know the medicines you take. Keep a list of your medicines and show them to your healthcare provider and pharmacist when you get a new medicine.**

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*The Important Safety Information does not include all the information needed to use DANZITEN safely and effectively. Please see accompanying [Full Prescribing Information](#) for DANZITEN.*

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*To Report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-800-461-7449, or FDA at 1-800-FDA-1088 or [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).*

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