ONE TIME ONLY

FIRST MONTH FREE OFFER
ONE PER PATIENT PER LIFETIME*

BIN#	610524	Group#	40028208
PCN#	1016	MEM ID#	**1442210554**

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 kinase inhibitor indicated for the treatment of:

- Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.

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)**

ADDITIONAL IMPORTANT SAFETY INFORMATION

Contraindications

DANZITEN is contraindicated in patients with hypokalemia, hypomagnesemia, or long QT syndrome.

Warnings and Precautions

Substitution With Other Nilotinib Products and Risk of Medication Errors: DANZITEN tablets may not be substitutable with other nilotinib products, including other nilotinib tablets, on a milligram per milligram basis. Confirm that the intended nilotinib product is being prescribed and dispensed.

Myelosuppression: Monitor complete blood count (CBC) during therapy and manage by treatment interruption or dose reduction.

Cardiac and Arterial Vascular Occlusive Events: Evaluate cardiovascular status, monitor and manage cardiovascular risk factors during DANZITEN therapy.

Pancreatitis and Elevated Serum Lipase: Monitor serum lipase; if elevations are accompanied by abdominal symptoms, interrupt doses and consider appropriate diagnostics to exclude pancreatitis.

Hepatotoxicity: Monitor hepatic function tests monthly or as clinically indicated.

Electrolyte Abnormalities: DANZITEN can cause hypophosphatemia, hypokalemia, hyperkalemia, hypocalcemia, and hyponatremia. Correct electrolyte abnormalities prior to initiating DANZITEN and monitor periodically during therapy.

Tumor Lysis Syndrome: Maintain adequate hydration and correct uric acid levels prior to initiating therapy with DANZITEN.

Hemorrhage: Hemorrhage from any site may occur. Advise patients to report signs and symptoms of bleeding and medically manage as needed.

Fluid Retention: Monitor patients for unexpected rapid weight gain, swelling, and shortness of breath. Manage medically.

Effects on Growth and Development in Pediatric Patients: Growth retardation has been reported in pediatric patients treated with nilotinib. Monitor growth and development in pediatric patients.

Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of potential risk to a fetus and to use effective contraception.

Treatment Discontinuation: Patients must have typical BCR-ABL transcripts. An FDA-authorized test with a detection limit below MR4.5 must be used to determine eligibility for discontinuation. Patients must be frequently monitored by the FDA authorized test to detect possible loss of remission.

Adverse Reactions

The most commonly reported non-hematologic adverse reactions (≥20%) in adult patients are nausea, rash, headache, fatigue, pruritus, vomiting, diarrhea, cough, constipation, arthralgia, nasopharyngitis, pyrexia, and night sweats. Hematologic adverse drug reactions include myelosuppression: thrombocytopenia, neutropenia, and anemia.

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

Drug Interactions

Strong CYP3A Inhibitors: Avoid concomitant use, including grapefruit juice with DANZITEN or reduce DANZITEN dose if concomitant use cannot be avoided.

Strong CYP3A Inducers: Avoid concomitant use with DANZITEN.

Proton Pump Inhibitors: Use short-acting antacids or H2 blockers as an alternative to proton pump inhibitors.

See Full Prescribing Information for Specific Drugs and Interactions.

Use in Specific Populations

Lactation: Advise women not to breastfeed.

Pediatric Use: The safety and effectiveness of nilotinib in pediatric patients below the age of 1 year with newly diagnosed, or who are resistant to or intolerant to Ph+ CML in chronic phase and accelerated phase have not been established.

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.

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.

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