Danziten™ (nilotinib) tablets 71mg, 95mg

Danziten CONNECT℠ PROGRAM ENROLLMENT FORM

Danziten CONNECT℠ Patient Support will provide the following services for eligible patients:

- Danziten CONNECT℠ Live Access & Reimbursement Team Member available to HCP/Office Staff
- Insurance Determination & Coverage Review (includes Benefits Verification, Prior Authorization)
- Financial Support (includes First FREE Month Offer and Co-Pay Program)
- Patient Assistance Program (PAP)

For assistance, please complete this form and fax it to **1-832-601-6158**.
You can also call **1-877-765-1130**, Mon-Fri 8am–8pm ET, to speak with a Danziten CONNECT℠ Team Member.
Visit our website at **www.Danziten.com**

*Indicates required field

Please attach insurance card image.

REQUESTED INVESTIGATION (Select one option ONLY)

☐ **Pharmacy Dispense:** Run Insurance Benefits Investigation and dispense DANZITEN™ (nilotinib) through Specialty Pharmacy

☐ **Benefit Investigation:** Run Insurance Benefits Investigation

PATIENT INFORMATION

*Patient Name (Last, First):

*Date of Birth: *Gender: M ☐ F ☐

*Address:

*City: *State: *Zip

Guardian Name (Last, First):

Guardian Email:

Guardian Phone: Secondary Number:

PRESCRIPTION INFORMATION

Drug: **Danziten™ (nilotinib)** **71 mg** ☐ **95 mg** ☐ Date:

Quantity: Refills:

Directions:

Diagnosis Code(s):

Patient Naive to Kinase Inhibitor therapy: ☐ Yes ☐ No

Product(s) used:

***Prescriber's Signature**

PHARMACY INSURANCE INFORMATION

*Insurance Name: Pharmacy Help Desk #:

Policyholder Name: *Relationship to Patient:

*Member ID #: *Group ID #:

*Rx BIN #: *PCN #:

MEDICAL INSURANCE INFORMATION

*Primary Insurance: *Phone:

*Member ID: *Group ID:

Secondary Insurance: Phone:

Member ID: Group ID:

PRESCRIBER INFORMATION

*Prescriber Name (Last, First):

*NPI:

*Prescriber Phone: *Fax:

*Address:

*City: *State: *Zip:

PRESCRIBER OFFICE CONTACT INFORMATION

*Office Contact Name (Last, First):

*Phone:

PROVIDER ATTESTATION

By my signature below, I verify that the information being disclosed in this enrollment form is complete and accurate to the best of my knowledge. I understand that Danziten CONNECT reserves the right at any time and for any reason, without notice, to modify this enrollment form or to modify or discontinue any services or assistance provided through this Program. Finally, I authorize Danziten CONNECT as my designated agent to use and disclose my patient's protected health information as may be necessary for treatment, payment, and healthcare operations, including to verify the accuracy of any information provided, to verify patient eligibility, to provide for payment and reimbursement, and to forward the above prescription information, by fax or other mode of delivery, to a pharmacy for fulfillment. I allow Danziten CONNECT to email me regarding prescription status updates and act as my prior authorization agent in dealing with prescription and medical insurance companies.

***Prescriber's Signature**

***Date of Signature**

Please see Important Safety Information, including Box Warning on the next page

MORE

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PATIENT AUTHORIZATION

Authorization for Use and Disclosure of Protected Health Information

I authorize Azurity Pharmaceuticals, companies working with Azurity Pharmaceuticals, my healthcare provider and pharmacy to use and disclose to Azurity Pharmaceuticals, and companies working with Azurity Pharmaceuticals, my Protected Health Information ("PHI"), such as information provided on the DANZITEN Patient Enrollment Form, my prescription, insurance, and medical therapy information. I authorize the disclosure of my PHI to specific individuals who are identified on the DANZITEN Patient Enrollment Form. I understand that the companies working with Azurity Pharmaceuticals, including my pharmacy, may receive payment for the use and disclosure of my PHI. I understand that I do not have to agree to the use and disclosure of my PHI in order to receive DANZITEN. While my PHI will be protected and used and disclosed only for the intended purposes, I understand that once it is disclosed, it may be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure. I understand that I may revoke this authorization to use or disclose my PHI by contacting a Danziten CONNECT representative by telephone 1-877-765-1130 or by mailing a letter to Azurity Pharmaceuticals, Inc. 8 Cabot Road, Suite 2000 Woburn, MA 01801 Attn: Legal Department.
By signing below, I authorize the use and disclosure of my Protected Health Information as explained above. If you are signing this Authorization as a personal representative of the person to receive DANZITEN, please state your relationship (e.g., "spouse," "sibling," "Legal Guardian").

*Print Patient Name:

*Print Name of Legal Guardian (if applicable):

*Relationship to Patient (if applicable):

***Legal Guardian's Signature** (if applicable)**:**

***Date of Signature:**

IMPORTANT SAFETY INFORMATION

DANZITENTM (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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