Danziten CONNECT℠

# Your trusted guide on your patient's CML treatment journey.

Your first step to ongoing support, we're with you every day and every way possible.

## Enroll Your Patient in Danziten CONNECT℠

- **Step 1:** Download the form
- **Step 2:** Fax the form to (832) 601-6158
- **Step 3:** Receive comprehensive support for your patients

Get your patients started by downloading and completing the Enrollment Form and faxing to (832) 601-6158

**Call 1-877-765-1130 to speak to a Danziten CONNECT℠ representative for more information**

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

### First Month Free

Eligible patients[a] may receive their first month free, which will allow them to start their treatment quickly

### May Pay As Little As $0 Co-Pay

Commercially insured eligible patients[a] may pay as low as $0 each month

*Subject to annual maximum*

### Support Programs

- Benefits Investigation
- Prior Authorization
- Financial Assistance
- Patient Assistance Program (PAP)

*Patients who meet eligibility criteria[a] may qualify to receive Danziten™ at no cost*

**Eligible patients may qualify to enroll in each program individually**

[a]Learn more about our Danziten CONNECT™ Program and Terms and Conditions by scanning the QR code

## Danziten™ is a kinase inhibitor indicated for the treatment of[1]:

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

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.

## 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)**

1 **Please see Important Safety Information on pages 3 & 4, and full Prescribing Information, including Boxed Warning.**

Danziten™ (nilotinib) tablets 71mg, 95mg

azurity pharmaceuticals

# Danziten™: Prior Authorization (PA) Submission Checklist

As with most branded medications, your patient's health plan will likely require a Prior Authorization (PA) before it approves Danziten™. The checklist below provides basic guidance on what may be needed to obtain a PA decision. It's important to note that PA requirements will vary among insurers. We encourage health providers to review PA guidelines on the insurer's website or to contact the insurer's customer service department to confirm requirements, forms, and contacts.

Use of this checklist does not guarantee coverage nor does it guarantee that a health plan will provide reimbursement for Danziten™ and is not intended to be a substitute for or to influence the independent medical judgment of the healthcare provider.

## 1. Find the appropriate PA form by insurance provider or state specific

- ☐ Contact the Provider Relations, Prior Authorization, Utilization Management phone number on the back of the patient's medical or pharmacy insurance card to obtain the appropriate PA form and submission process
- ☐ Healthcare providers may utilize an electronic Prior Authorization (ePA) solution for PA submission directly to the payer/insurance
- ☐ Healthcare providers may contact the Danziten CONNECT℠ team at 1-877-765-1130 for assistance with PA submission to the insurance

## 2. If the information below is not part of the PA request form, it may be beneficial to provide the following to the insurer:

- ☐ Patient demographics and information: Name, date of birth, gender, and insurance policy
- ☐ Previous therapy history: Tried and failed tyrosine kinase inhibitor (TKI) medications for Ph+CML including reasons for discontinuation of therapies and the dates
- ☐ Summary of diagnosis history: Clinical documentation of Ph+CML diagnosis, ICD-10 code(s), date of diagnosis, and any CML mutation status
- ☐ Rationale for Danziten™: Medical necessity or clinical rationale for the use of Danziten™ including why other therapies for Ph+CML may not be appropriate
- ☐ Clinical documentation and progress notes: Any history of TKI intolerance, resistance, or contraindication, treatment goals, and testing history with results and dates

## 3. Clinical data to support the use of Danziten™, such as:

- ☐ Applicable National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in oncology (NCCN Guidelines®)
- ☐ Efficacy and safety trial data from clinical trials
- ☐ Confirmation that the patient does not have contraindicated mutations A337T, P465S, or F359V/C/I

*For expedited requests, adequate information should be provided to support the urgent nature of the request. Specific prior authorization forms may need to be completed for select products or therapeutic areas. Always verify that the correct form has been completed.*



**Please see Important Safety Information on pages 3 & 4, and full Prescribing Information, including Boxed Warning.**

# 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 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.***

# Danziten™: Finally, a Nilotinib With No Mealtime Restrictions

## Make Danziten™ Your Nilotinib of Choice

Danziten™ (nilotinib) tablets 71mg, 95mg

azurity® pharmaceuticals

**Reference:** DANZITEN [prescribing information]: Woburn, MA: Azurity Pharmaceuticals, Inc; 2024.