

Danziten (nilotinib) – New drug approval

- On November 7, 2024, the [FDA approved](#) Azurity Pharmaceuticals' [Danziten \(nilotinib\)](#) tablets, for the treatment of adult patients with:
 - Newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
 - Chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib.
- Additional pediatric use information is approved for Novartis' [Tasigna[®] \(nilotinib\)](#) capsules. However, due to Novartis' marketing exclusivity rights, Danziten is not labeled with that pediatric information.
- The effectiveness of Danziten tablets was established based on adequate and well-controlled studies of Tasigna capsules, which have a different recommended dosage than Danziten.
- Danziten carries a boxed warning for QT prolongation and sudden deaths.
- Danziten is contraindicated in patients with hypokalemia, hypomagnesemia, or long QT syndrome.
- Additional warnings and precautions for Danziten include substitution with other nilotinib products and risk of medication errors; myelosuppression; cardiac and arterial vascular occlusive events; pancreatitis and elevated serum lipase; hepatotoxicity; electrolyte abnormalities; tumor lysis syndrome; hemorrhage; total gastrectomy; monitoring laboratory tests; fluid retention; effects on growth and development in pediatric patients; embryo-fetal toxicity; and monitoring of BCR-ABL transcript levels.
- The most common non-hematologic adverse reactions ($\geq 20\%$) with Danziten use in adults 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.
- The recommended dosage of Danziten in adult patients with newly diagnosed Ph+ CML is 142 mg orally twice daily. The recommended dosage in adult patients with resistant or intolerant Ph+ CML is 190 mg orally twice daily.
 - Danziten may not be substitutable with other nilotinib products on a milligram per milligram basis.
 - Refer to the Danziten drug label for complete dosing and administration recommendations.
- Azurity Pharmaceuticals' launch plans for Danziten are pending. Danziten will be available as a 71 mg and 95 mg tablet.