

## Tasigna® (nilotinib) - First-time generic

- On May 27, 2025, <u>Apotex launched</u> an <u>AB-rated</u> generic version of Novartis' <u>Tasigna (nilotinib)</u> capsules.
  - Apotex was granted 180-days of generic exclusivity for its generic Tasigna.
- Tasigna is approved for the:
  - Treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
  - Treatment of adult patients with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib
  - Treatment of pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Ph+ CML with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.
- Tasigna carries a boxed warning for QT prolongation and sudden deaths.



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