

Sprycel[®] (dasatinib) – Expanded orphan indication

- On November 10, 2017, [Bristol-Myers Squibb announced](#) the FDA approval of [Sprycel \(dasatinib\)](#) tablets, for the treatment of pediatric patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- Sprycel is also indicated for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase; chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including [imatinib](#); and Ph+ acute lymphoblastic leukemia with resistance or intolerance to prior therapy.
- Sprycel was evaluated in two pediatric studies involving 97 patients with chronic phase CML, including newly diagnosed patients and those resistant or intolerant to previous treatment with imatinib. The efficacy endpoints included complete cytogenetic response (CCyR), major cytogenetic response (MCyR), and major molecular response (MMR).
 - Overall, the studies showed an increasing trend for response for CCyR, MCyR, and MMR across time (3 – 24 months). The increasing trend in response was seen in newly diagnosed and imatinib resistant/intolerant patients.
 - Furthermore, with a median follow-up of 4.5 years in newly diagnosed patients and 5.2 years in imatinib resistant/intolerant patients, the median durations of CCyR, MCyR, and MMR could not be estimated as more than half of responders had not progressed at the time of the data cut-off.
- The safety profile of Sprycel in pediatric patients was comparable to that reported in studies in adult subjects with chronic phase CML. However, bone growth and development should be monitored in pediatric patients.
- In pediatric patients, the recommended dosage of Sprycel in chronic phase CML is based on body weight.

Body weight (kg)	Daily dose (mg)
10 to < 20 kg	40 mg
20 to < 30 kg	60 mg
30 to < 45 kg	70 mg
≥ 45 kg	100 mg

- Tablet dosing is not recommended in patients weighing < 10 kg.
- Tablets should be swallowed whole. Do not crush, cut, or chew tablets.
- For the recommended dosage of Sprycel in other FDA-approved indications, refer to the drug label.