Sprycel® (dasatinib) – Expanded indication

- On December 21, 2018, the FDA approved Bristol-Myers Squibb's Sprycel (dasatinib) tablets, for the treatment of pediatric patients 1 year of age and older with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.
    - Sprycel was previously approved in pediatric patients with Ph+ chronic myeloid leukemia (CML) in chronic phase.
- Sprycel is also approved 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
    - Ph+ ALL with resistance or intolerance to prior therapy.
- The approval of Sprycel's expanded indication was based on a single cohort (cohort 1) of study CA180372, a multiple-cohort study of pediatric patients with newly diagnosed B-cell precursor Ph+ ALL. The 78 patients in cohort 1 received Sprycel for up to 24 months in combination with chemotherapy. Efficacy was established on the basis of 3-year event-free survival (EFS), defined as the time from the start of Sprycel to lack of complete response at the end of the third high risk block, relapse, secondary malignancy, or death from any cause.
    - The 3-year EFS binary rate was 64.1% (95% CI: 52.4, 74.7).
    - At the end of induction, 75 patients (96%) had a bone marrow with < 5% lymphoblasts, and 76 patients (97%) achieved this by the end of consolidation.
- The most common adverse reactions (≥ 30%) in pediatric patients receiving Sprycel in combination with chemotherapy included mucositis, febrile neutropenia, pyrexia, diarrhea, nausea, vomiting, musculoskeletal pain, abdominal pain, cough, headache, rash, fatigue, constipation, arrhythmia, hypertension, edema, infections (bacterial, viral and fungal), hypotension, decreased appetite, hypersensitivity, dyspnea, epistaxis, peripheral neuropathy, and altered state of consciousness.
- The recommended starting dosage for Sprycel in pediatric patients with Ph+ ALL is weight-based, orally once daily, with or without food.

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

    - Sprycel therapy should begin on or before day 15 of induction chemotherapy, when diagnosis is confirmed and should be continued for 2 years.
    - Tablet dosing is not recommended for patients weighing less than 10 kg.
    - The dose should be recalculated every 3 months based on changes in body weight, or more often if necessary.
    - Refer to the Sprycel drug label for recommendations on dose escalation.

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- Refer to the Sprycel drug label for dosing recommendations for its other indications.