

Authorization with conditions of ^PSPRYCEL* for the treatment of adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase

Fact Sheet

What is SPRYCEL?

SPRYCEL is a drug containing an active ingredient called dasatinib. It is available as 20, 50, 70, 80, 100 and 140 mg film coated tablets.

Health Canada has authorized SPRYCEL with conditions, under the Notice of Compliance with Conditions (NOC/c) Policy, for the treatment of adults with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase. This authorization reflects the promising nature of the clinical evidence and safety which must be verified and/or extended with further studies. Products, authorized under Health Canada's NOC/c Policy, have demonstrated promising benefit, are of high quality, and possess an acceptable safety profile based on a benefit/risk assessment.

What is SPRYCEL used for?

SPRYCEL is used for the treatment of adults with newly diagnosed Ph+CML in chronic phase.

SPRYCEL have also been granted marketing authorization without conditions for the treatment of adults with:

- Philadelphia chromosome positive (Ph+) chronic, accelerated, or blast phase chronic myeloid leukemia (CML) who are no longer benefiting from other available therapies for CML including imatinib mesylate (Gleevec®)
- Ph+ acute lymphoblastic leukemia (ALL) who have had prior therapy.

What is Chronic Myeloid Leukemia?

Chronic myeloid leukemia or CML is one form of leukemia. In CML, myeloid white blood cells multiply in an uncontrolled manner. It may take years for CML to progress because it is a slow-growing or chronic cancer. There are three phases of CML: chronic phase, accelerated phase, and blast crisis phase. As CML progresses, patients advance through these phases.

How does SPRYCEL work?

Dasatinib acts by inhibiting the activity of proteins within the leukemia cells of patients with CML. These proteins are responsible for the uncontrolled growth of the leukemia cells.

What do patients need to know about using SPRYCEL?

SPRYCEL should be given under the supervision of a doctor experienced in the use of anti-cancer drugs

BEFORE and during treatment with SPRYCEL, patients should tell their doctor if they:

- are pregnant or planning to become pregnant. SPRYCEL may harm the fetus when given to a pregnant woman. Women should avoid becoming pregnant while undergoing treatment with SPRYCEL.
- are breast-feeding. It is not known if SPRYCEL can pass into your breast milk or if it can harm your baby. Do not breast-feed if you are taking SPRYCEL.
- are a sexually active male. Men who take SPRYCEL are advised to use a condom to avoid pregnancy in their partner.
- have a liver or heart problem, such as arrhythmia (irregular heartbeat), long QT syndrome (a hereditary disorder of the heart electrical rhythm).
- are lactose intolerant or have been diagnosed with an intolerance to some sugars.
- have muscle aches/pains or weakness, or dark-colored urine

The safety and efficacy of SPRYCEL in children have not been established.

Can SPRYCEL be taken with other drugs?

SPRYCEL may interact with other drugs. Patients must tell their doctor or pharmacist about all drugs, including prescription and non-prescription drugs, herbal products (e.g. St. John's Wort) and supplements they are taking or planning to take before they take SPRYCEL, especially medicines to thin the blood or prevent clots such as warfarin or aspirine.

While taking SPRYCEL patients should avoid taking medicines that reduce stomach acid such as cimetidine, famotidine, ranitidine, or omeprazole while taking SPRYCEL since the absorption of SPRYCEL from the stomach into the bloodstream is best accomplished in the presence of stomach acid. Medicines that neutralize stomach acid, such as aluminium hydroxide/magnesium hydroxide, calcium carbonate or calcium carbonate and magnesia may be taken up to 2 hours before or 2 hours after SPRYCEL.

What are the side effects and how serious are they?

Like all medicines, SPRYCEL can cause side effects.

Serious side effects with the use of SPRYCEL include:

- Decrease of the production of blood cells (myelosuppression)
- Bleeding which may result in death
- Fluid retention including fluid in the lung (pleural effusion), fluid around the heart (pericardial effusion)
- Congestive heart failure, the symptoms include shortness of breath, swelling, weight gain and pulmonary edema (fluid in the lung)

Common side effects with the use of SPRYCEL include diarrhea, fever, headache, fatigue, nausea, skin rash, shortness of breath, cough, vomiting, pain, stomach pain, infection, upper respiratory tract infection, muscle aches, joint aches, and bone and extremity pain.

Who should not be treated with SPRYCEL?

SPRYCEL tablets should not be taken by patients with a history of allergic reactions to dasatinib or to any other ingredients in SPRYCEL.

How is SPRYCEL taken?

The usual starting dose for **newly diagnosed Ph+CML in chronic phase** is 100 mg taken by mouth once a day, either in the morning or in the evening. The tablets should be swallowed whole, not crushed. They can be taken with or without food. Try to take SPRYCEL at the same time each day.

Avoid taking grape fruit juice since it may increase the blood levels of SPRYCEL.

What else should patients know about taking SPRYCEL?

SPRYCEL tablets should be stored at room temperature between 15°–30° C.

Where can I learn more about SPRYCEL?

Additional information about SPRYCEL can be obtained by calling the Medical Information department at 866-463-6267 or by talking to your doctor.

This document plus the full product monograph and Patient Information can be obtained on Bristol-Myers Canada's website (www.bmscanada.ca)

Patient Support Program:

Bristol-Myers Squibb Canada offers a patient support program to all Canadian patients who have been prescribed SPRYCEL as indicated in the Product Monograph. The services, offered at no cost, include information on CML and reimbursement navigation assistance. The program is fully confidential. For more information, please call toll-free at 1-877-967-6626.

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