

PATIENT INFORMATION
SPRYCEL® (Spry-sell)
(dasatinib)
Tablets

Read the Patient Information that comes with SPRYCEL before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is SPRYCEL (dasatinib)?

SPRYCEL® is a prescription medicine used to treat adults who have:

- newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including Gleevec® (imatinib mesylate).
- Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment.

It is not known if SPRYCEL is safe and effective in children younger than 18 years old.

What should I tell my healthcare provider before taking SPRYCEL?

Before you take SPRYCEL, tell your healthcare provider if you:

- have problems with your immune system
- have liver problems
- have heart problems
- are lactose intolerant
- have any other medical conditions
- are pregnant or planning to become pregnant. SPRYCEL may harm your unborn baby. Women should not become pregnant while taking SPRYCEL. Talk to your healthcare provider right away if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if SPRYCEL passes into your breast milk or if it can harm your baby. You and your healthcare provider should decide if you will take SPRYCEL or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, antacids, and herbal supplements.

Especially tell your healthcare provider if you take:

- medicines that increase the amount of SPRYCEL in your bloodstream, such as:**

Nizoral® (ketoconazole),	Nefazodone (serzone, nefadar),
Sporanox® (itraconazole),	Invirase® (saquinavir),
Norvir® (ritonavir),	Ketek® (telithromycin),
Reyataz® (atazanavir sulfate),	E-mycin® (erythromycin),
Crixivan® (indinavir),	Biaxin® (clarithromycin).
Viracept® (nelfinavir),	

- medicines that decrease the amount of SPRYCEL in your bloodstream, such as:**

Decadron® (dexamethasone),	Rimactane® (rifampin),
Dilantin® (phenytoin),	Luminal® (phenobarbital).
Tegretol® (carbamazepine),	

- medicines whose blood levels might change by taking SPRYCEL, such as:**

Sandimmune® (cyclosporine),	Rapamune® (sirolimus),
Alfenta® (alfentanil),	Prograf® (tacrolimus),
Fentanyl® (fentanyl),	Ergomar® (ergotamine).
Orap® (pimozide),	

SPRYCEL is best absorbed from your stomach into your bloodstream in the presence of stomach acid. You should avoid taking medicines that reduce stomach acid, such as:

Tagamet® (cimetidine),	Protonix® (pantoprazole sodium),
Pepcid® (famotidine),	Nexium® (esomeprazole),
Zantac® (ranitidine),	AcipHex® (rabeprazole),
Prilosec® (omeprazole),	Prevacid® (lansoprazole).

Medicines that neutralize stomach acid, such as Maalox® (aluminum hydroxide/magnesium hydroxide), Tums® (calcium carbonate), or Roloids® (calcium carbonate and magnesia), may be taken up to 2 hours before or 2 hours after SPRYCEL.

Since SPRYCEL therapy may cause bleeding, tell your healthcare provider if you are using blood thinner medicine, such as Coumadin® (warfarin sodium) or aspirin.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take SPRYCEL?

Take SPRYCEL exactly as prescribed by your healthcare provider.

- Take SPRYCEL with or without food. Try to take SPRYCEL at the same time each day.
- Swallow SPRYCEL tablets whole. Do not break, cut, or crush the tablets.
- You should not drink grapefruit juice while taking SPRYCEL.
- Your healthcare provider may:**
 - change your dose of SPRYCEL or
 - tell you to temporarily stop taking SPRYCEL.
- Do not change your dose or stop taking SPRYCEL without first talking with your healthcare provider.**
- If you miss a dose of SPRYCEL,** take your next scheduled dose at its regular time. Do not take two doses at the same time. Call your healthcare provider or pharmacist if you are not sure what to do.
- If you take too much SPRYCEL,** call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of SPRYCEL?

SPRYCEL may cause serious side effects, including:

- Low Blood Cell Counts:** SPRYCEL may cause low red blood cell counts (anemia), low white blood cell counts (neutropenia), and low platelet counts (thrombocytopenia). Your healthcare provider will do blood tests to check your blood cell counts regularly during your treatment with SPRYCEL. Call your healthcare provider right away if you have a fever or any signs of an infection while taking SPRYCEL.
- Bleeding:** SPRYCEL may cause severe bleeding that can lead to death. Call your healthcare provider right away if you have:
 - unusual bleeding or bruising of your skin
 - bright red or dark tar-like stools
 - a decrease in your level of consciousness, headache, or change in speech.

- **Your body may hold too much fluid (fluid retention):** In severe cases, fluid may build up in the lining of your lungs, the sac around your heart, or your stomach cavity. Call your healthcare provider right away if you get any of these symptoms during treatment with SPRYCEL:
 - swelling all over your body
 - weight gain
 - shortness of breath and cough.
- **Heart problems.** SPRYCEL may cause an abnormal heart rate, heart problems or a heart attack. Your healthcare provider will monitor the potassium and magnesium levels in your blood, and your heart function.
- **Pulmonary Arterial Hypertension (PAH).** SPRYCEL may cause high blood pressure in the vessels of your lungs. PAH may happen at anytime during your treatment with SPRYCEL. Your healthcare provider should check your heart and lungs before and during your treatment with SPRYCEL. Call your healthcare provider right away if you have shortness of breath, tiredness, or swelling all over your body (fluid retention).

Other common side effects of SPRYCEL therapy include:

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|-------------|---------------|
| • diarrhea | • tiredness |
| • headache | • vomiting |
| • cough | • muscle pain |
| • skin rash | • weakness |
| • fever | • infections |
| • nausea | |

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of SPRYCEL. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SPRYCEL?

- Store SPRYCEL at room temperature, between 68°F to 77°F (20°C to 25°C).
- Ask your healthcare provider or pharmacist about the right way to throw away outdated or unused SPRYCEL.
- Women who are pregnant should not handle crushed or broken SPRYCEL tablets.
- **Keep SPRYCEL and all medicines out of the reach of children and pets.**

General information about SPRYCEL

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use SPRYCEL for a condition for which it is not prescribed. Do not give SPRYCEL to other people even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about SPRYCEL. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about SPRYCEL that is written for healthcare professionals.

For more information, go to www.sprycel.com or call 1-800-332-2056.

What are the ingredients in SPRYCEL?

Active ingredient: dasatinib


Inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, and magnesium stearate. The tablet coating consists of hypromellose, titanium dioxide, and polyethylene glycol.

This Patient Package Insert has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

Revised: October 2011

 Bristol-Myers Squibb
Princeton, NJ 08543 U.S.A.

1284903A0

Rev October 2011

DS-B0001B-10-11