



Patient Information Sheet

Dasatinib (marketed as Sprycel)

This is a summary of the most important information about Sprycel. For details, talk to your healthcare professional.

What Is Sprycel?

Sprycel is a prescription medicine used to treat adults who:

- have chronic myeloid leukemia (CML)
- have acute lymphoblastic leukemia (ALL) called Philadelphia chromosome positive or Ph+ALL
- are no longer benefiting from treatment with the current available therapies for these diseases including a medicine called Gleevec (imatinib mesylate)
- experience severe side effects from Gleevec and are no longer able to take it

The long term benefits and toxicities are currently still being studied.

Sprycel has not been studied in children.

Who Should Not Take Sprycel?

You should not take Sprycel if you:

- have not previously had a trial of Gleevec (imatinib mesylate)
- are pregnant or planning to become pregnant

What Are The Side Effects?

The following are the major side effects of Sprycel therapy. However, this list is not complete.

- **Low Blood Counts.** Sprycel may cause low red blood cell counts (anemia), low white blood cell counts (neutropenia), and low platelet counts (thrombocytopenia). Your healthcare professional will monitor your blood counts frequently after your start Sprycel, and may adjust your dose of Sprycel or withhold the drug temporarily in the event your blood counts drop too low. In some cases, you may need to receive transfusions of red blood cells or platelets. **Notify your healthcare professional immediately if you develop a fever while taking Sprycel.**

- **Bleeding: Sprycel may cause bleeding.** The most serious bleeding events observed in clinical studies included bleeding into the brain leading to death in 1% of patients, and bleeding from the gastrointestinal tract. Less severe events included bleeding from the nose, the gums, bruising of the skin, and excessive menstrual bleeding. **Notify your healthcare professional immediately if you experience bleeding or easy bruising while taking Sprycel.**
- **Fluid Retention:** Sprycel may cause fluid to accumulate in your legs and around your eyes. In more severe cases, fluid may accumulate in the lining of your lungs, the sac around your heart, or your abdominal cavity. **Notify your healthcare professional immediately if you experience swelling, weight gain, or increasing shortness of breath while taking Sprycel.**
- **Some common side effects** that may occur with Sprycel include:
 - diarrhea
 - skin rash
 - headache
 - fatigue
 - nausea

What Should I Tell My Healthcare Professional?

Before you start taking Sprycel, tell your healthcare professional if you:

- **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. Tell your healthcare professional immediately if you become pregnant or plan to become pregnant while taking 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.
- are lactose intolerant.





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Can Other Medicines Or Food Affect Sprycel?

Sprycel and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Sprycel is eliminated from your body through the liver. The use of certain other medicines may alter the levels of Sprycel in your bloodstream. Likewise, levels of other medicines in your bloodstream can be affected by Sprycel. Such changes can increase the side effects, or reduce the activity of the medicines you are taking, including Sprycel.

Especially tell your healthcare professional if you take:

- medicines that increase the amount of Sprycel in your bloodstream, such as Nizoral (ketoconazole), Sporanox (itraconazole), Norvir (ritonavir), Reyataz (atazanavir sulfate), Crixivan (indinavir), Viracept (nelfinavir), Invirase (saquinavir), Ketek (telithromycin), E-Mycin (erythromycin), and Biaxin (clarithromycin).
- medicines that decrease the amount of Sprycel in your bloodstream, such as Decadron (dexamethasone), Dilantin (phenytoin), Tegretol (carbamazepine), Rimactane (rifampicin), and Luminal (Phenobarbital).
- medicines whose blood levels might be altered by Sprycel, such as Sandimmune (cyclosporine), Alfenta (alfentanil), fentanyl, Orap (pimozide), Rapamune (sirolimus), Prograf (tacrolimus), and Ergomar (ergotamine).
- medicines that reduce stomach acid, such as Tagamet (cimetidine), Pepcid (famotidine), Zantac (ranitidine), Prilosec (omeprazole), Protonix (pantoprazole), Nexium

(esomeprazole), Aciphex (rabeprazole), and Prevacid (lansoprazole).

- medicines that neutralize stomach acid, such as Maalox (aluminum hydroxide/magnesium hydroxide), Tums (calcium carbonate), Rolaids (calcium carbonate and magnesium).
- medicines that thin the blood, such as Coumadin (warfarin sodium) and aspirin.

How Should I Take Sprycel?

- The usual dose is 70 mg (one 70-mg tablet) twice daily, once in the morning and once in the evening, with or without a meal. Try to take Sprycel at the same time each day.
- Take Sprycel whole. Do not break, cut, or crush the tablets.
- Depending on your response to treatment and any side effects that you may experience, your healthcare professional may adjust your dose of Sprycel upward or downward, or may temporarily discontinue Sprycel.
- You should not change your dose or stop taking Sprycel without first talking with your healthcare professional.
- 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 professional or pharmacist if you are not sure what to do.
- If you accidentally take more than the prescribed dose of Sprycel, call your healthcare professional right away.

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