

UNDERSTANDING SIDE EFFECTS

and the importance of working with your healthcare team

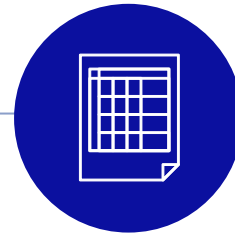
This brochure will help you



Know more about possible side effects



Discuss side effects with your healthcare team



Keep track of any side effect you may experience

The information provided in this brochure is not a substitute for your healthcare team's advice.

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What is SPRYCEL?

SPRYCEL[®] (dasatinib) is a prescription medicine used to treat:

- ✓ Adults with newly diagnosed Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP)
- ✓ Adults with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib
- ✓ Adults with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment
- ✓ Children 1 year of age and older with Ph+ CML in chronic phase
- ✓ Children 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy

It is not known if SPRYCEL is safe and effective in children under 1 year of age.

SPRYCEL may cause serious side effects, including low blood cell counts, bleeding problems, fluid retention, heart and blood vessel (cardiovascular) problems, pulmonary arterial hypertension, severe skin reactions, tumor lysis syndrome, slowing of growth and development in children, and liver problems. Side effects of SPRYCEL that are considered most common in adults and children receiving SPRYCEL alone include: diarrhea, headache, skin rash, shortness of breath, tiredness, nausea, and muscle pain.

Please see the Important Safety Information included on pages 7 to 12 of this brochure, and, for more in-depth safety information, please read the **Patient Information in the full Prescribing Information.**

WHAT ARE THE SIDE EFFECTS TO LOOK OUT FOR?

Medications like SPRYCEL can cause side effects, or undesired effects that people may experience. For instance, people may experience diarrhea, cramping, or fatigue—it can vary from person to person.

Be sure to talk to your doctor if you think you're having a side effect. Talk to your doctor soon, even if the side effect is minor. Your doctor may be able to help.

SERIOUS SIDE EFFECTS

SPRYCEL may cause serious side effects, including those listed below.



Call your healthcare provider right away if you have any symptoms of the side effects below, or any other concerns about these side effects:



Low blood cell counts



Pulmonary Arterial Hypertension (PAH)



Bleeding problems



Severe skin reactions



Your body may hold too much fluid (fluid retention)



Tumor Lysis Syndrome (TLS)



Heart and blood vessel (cardiovascular) problems



Slowing of growth and development in children



Liver problems

Side effects may be manageable with appropriate medical intervention. Please call your healthcare provider if you experience any of the above symptoms. Please see page 5 for additional information on side effect management.

In adults with newly diagnosed chronic phase Ph+ CML

SPRYCEL was approved for this condition based on a clinical trial comparing SPRYCEL to another treatment (imatinib). The goals of the study were to look at certain results and report on side effects. 260 people took SPRYCEL in the trial, and 259 took imatinib.

- Serious side effects were reported in 16.7% of SPRYCEL-treated patients
 - Serious side effects in 5% or more of patients included a 5% incidence of pleural effusion

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WHAT ARE THE SIDE EFFECTS TO LOOK OUT FOR?

MOST COMMON SIDE EFFECTS

These are the commonly observed side effects with SPRYCEL:



Diarrhea



Headache



Skin rash



Shortness of breath



Tiredness



Nausea



Muscle pain

If anything feels out of the ordinary—even a small cough or unusual tiredness—do not ignore it. Your healthcare team is your best resource to help with your treatment.

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Side effects may be manageable with appropriate medical intervention. Please call your healthcare provider if you experience any of the above symptoms. Please see page 5 for additional information on side effect management.

IMPORTANT SAFETY INFORMATION



Tell your healthcare provider about all the medicines you take, including:

- prescription and over-the-counter medicines
- vitamins
- antacids
- herbal supplements

What should I discuss with my healthcare provider before starting SPRYCEL?



Talk to your healthcare provider about all of your medical conditions, including if you have any of these medical conditions:

- problems with your immune system
- heart problems, including a condition called congenital long QT syndrome
- low potassium or low magnesium levels in your blood
- lactose (milk sugar) intolerance
- liver problems

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TALKING TO YOUR HEALTHCARE TEAM ABOUT SIDE EFFECTS

Why it is important to talk to them and how it can help you

Treating certain side effects early may help prevent them from becoming worse.

Your healthcare team are experts in managing side effects – they are always your best resource for help with your treatment.

What your healthcare team can do

Your team will work with you to help manage your side effects. They may:

- Give you other medicines to treat your symptoms
- Change your dose of SPRYCEL
- Temporarily stop treatment with SPRYCEL

Do not try to treat any possible side effects yourself. If you notice any discomfort or changes in the way you are feeling, contact your healthcare team immediately.

IMPORTANT FACTS ABOUT SPRYCEL



Tell your healthcare provider if you are:


- **Pregnant or plan to become pregnant.** SPRYCEL can harm your unborn baby.
 - **Females who can become pregnant:**
 - You should not become pregnant during treatment with SPRYCEL.
 - You should use effective birth control (contraception) during treatment and for 30 days after your last dose of SPRYCEL.
 - Talk to your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with SPRYCEL.
 - **Males with female partners who can become pregnant:**
 - You should use effective birth control (contraception) during treatment and for 30 days after your last dose of SPRYCEL.
 - Your female partner should call her healthcare provider if she becomes pregnant or thinks she is pregnant during your treatment with SPRYCEL.
 - **Breastfeeding or plan to breastfeed.** It is not known if SPRYCEL passes into your breast milk. You should not breastfeed during treatment and for 2 weeks after your last dose of SPRYCEL.

Females who are pregnant should not handle crushed or broken SPRYCEL tablets.

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QUESTIONS TO ASK ABOUT MANAGING SOME COMMON SIDE EFFECTS

Here are some ideas for the kinds of questions you may want to ask your healthcare team.

Side Effects/Questions for Your Doctor	Ask your doctor if these tips are right for you
 <p>Diarrhea</p> <ul style="list-style-type: none"> • How much liquid should I drink each day? • Are there certain foods I should eat? • Is there a medicine I can take that will help? 	<p>Eat small meals of foods that are easy to ingest (such as banana, rice, toast)</p>
 <p>Tiredness</p> <ul style="list-style-type: none"> • What can I do to feel less tired? • Are there exercises that could help? • Should I change something in my diet? 	<p>Take short naps or rest breaks if you can (30 minutes or less)</p>
 <p>Shortness of breath</p> <ul style="list-style-type: none"> • Are there activities I should avoid? • Are there breathing exercises I should try? 	<p>Contact your healthcare team (Shortness of breath or a cough may be an early sign of pleural effusion, which may be a sign of fluid near your lungs)</p>
 <p>Nausea</p> <ul style="list-style-type: none"> • Are there any medicines that may help? • Which foods should I avoid? 	<p>Drink clear, cold liquids and sip slowly</p>

SIDE EFFECT TRACKER

Use this page to keep track of any side effects you may have. You can print out the document, and keep track of any side effects when you need to. Share the information with your healthcare team, and use the right column to make a note of their advice.

Date	Side Effect(s)	Details	I contacted my healthcare team and they told me... <i>[Use this column to make notes on your healthcare team's advice]</i>
<i>Example:</i> 6/1	<i>Diarhea</i>	<i>Started after breakfast. Went to bathroom 4 times</i>	
<i>Example:</i> 8/7	<i>Felt out of breath</i>	<i>Winded after walking upstairs</i>	

Important Facts About SPRYCEL® (dasatinib)

This is a summary of important information that patients need to know about SPRYCEL. Your healthcare team can work with you to help answer any questions you may have about SPRYCEL. Keep this document in a safe place, so you can refer to it before and during your treatment.

Look out for the following icons as you read:



Talk to your healthcare provider



Call a healthcare provider right away



Helpful information to remember

What is SPRYCEL?

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- ✓ Adults with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib
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It is not known if SPRYCEL is safe and effective in children under 1 year of age.



Example SPRYCEL tablet. Tablet is not actual size.

Tablets are white to off-white, with “BMS” appearing on one side. These letters may be followed by a number indicating the strength of the tablet, in milligrams. In addition, an identification number will be marked on the other side. Size and shape may vary by dose. Tablets are taken by mouth.

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Important Facts About SPRYCEL[®] (dasatinib) *(continued)*

What should I discuss with my healthcare provider before starting SPRYCEL?



Talk to your healthcare provider about all of your medical conditions, including if you have any of these medical conditions:

- problems with your immune system
- heart problems, including a condition called congenital long QT syndrome
- low potassium or low magnesium levels in your blood
- lactose (milk sugar) intolerance
- liver problems



Tell your healthcare provider if you are:

- **Pregnant or plan to become pregnant.** SPRYCEL can harm your unborn baby.
 - **Females who can become pregnant:**
 - You should not become pregnant during treatment with SPRYCEL.
 - You should use effective birth control (contraception) during treatment and for 30 days after your last dose of SPRYCEL.
 - Talk to your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with SPRYCEL.
 - **Males with female partners who can become pregnant:**
 - You should use effective birth control (contraception) during treatment and for 30 days after your last dose of SPRYCEL.
 - Your female partner should call her healthcare provider if she becomes pregnant or thinks she is pregnant during your treatment with SPRYCEL.
 - **Breastfeeding or plan to breastfeed.** It is not known if SPRYCEL passes into your breast milk. You should not breastfeed during treatment and for 2 weeks after your last dose of SPRYCEL.

Females who are pregnant should not handle crushed or broken SPRYCEL tablets.



Tell your healthcare provider about all the medicines you take, including:

- prescription and over-the-counter medicines
- vitamins
- antacids
- herbal supplements

If you take an antacid medicine, take it 2 hours before or 2 hours after your dose of SPRYCEL.

SPRYCEL may interact with other medicines you are taking. This can change the relative effectiveness of SPRYCEL or cause unwanted side effects.



During treatment with SPRYCEL, make sure you also talk to your healthcare provider before you begin to take anything new. Your healthcare provider can help identify any potential interactions and help find alternatives.

Important Facts About SPRYCEL[®] (dasatinib) *(continued)*

How should SPRYCEL be taken?



Take SPRYCEL exactly as your healthcare provider tells you to take it. Your healthcare provider may change your dose of SPRYCEL or temporarily stop treatment with SPRYCEL. **Do not change your dose or stop taking SPRYCEL without first talking to your healthcare provider.**

- Do take SPRYCEL one (1) time a day
- Do take SPRYCEL with or without food, either in the morning or in the evening, at the same time each day*
- Do swallow SPRYCEL tablets whole with water
 - If your child cannot swallow tablets whole, talk to your healthcare provider
- Do not cut, crush, or chew the tablets
- Do not drink grapefruit juice during treatment with SPRYCEL
- Do not take St. John's wort during treatment with SPRYCEL

*Setting an alarm clock or a calendar notification is a great way to remember to take medication.

What if I miss a dose of SPRYCEL?

If you miss a dose of SPRYCEL, take your next scheduled dose at your regular time. Do not take two doses at the same time. Call your healthcare provider or your pharmacist if you are not sure what to do.

What if I take too much SPRYCEL?



Call your healthcare provider or go to the nearest hospital emergency room right away.

Important Facts About SPRYCEL[®] (dasatinib) *(continued)*

What are the possible side effects of SPRYCEL?

Serious side effects

SPRYCEL may cause serious side effects, including those listed below.



Call your healthcare provider right away if you have any symptoms of the side effects below, or any other concerns about these side effects:

- **Low blood cell counts:** Low blood cell counts are common with SPRYCEL and can be severe, including 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 any of these symptoms during treatment with SPRYCEL:
 - fever
 - any signs of an infection
- **Bleeding problems:** Bleeding problems are common with SPRYCEL. Sometimes these bleeding problems can be serious and lead to death. Call your healthcare provider right away if you have:
 - unusual bleeding or bruising of your skin
 - decreased alertness, headache, or change in speech
 - bright red or dark tar-like stools
- **Your body may hold too much fluid (fluid retention):** Fluid retention is common with SPRYCEL and can sometimes be severe. 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 have any of these symptoms during treatment with SPRYCEL:
 - swelling all over your body
 - dry cough
 - weight gain
 - chest pain when taking a deep breath
 - shortness of breath, especially if this happens with low levels of physical activity or at rest
- **Heart and blood vessel (cardiovascular) problems:** SPRYCEL may cause heart problems, including an abnormal heart rate, a heart attack, or small strokes that last only a few minutes or a few hours, called transient ischemic attacks (TIAs). TIAs are often a warning sign that you are at risk for a more serious stroke. Your healthcare provider will monitor the potassium and magnesium levels in your blood and your heart function.

Get medical help right away if you develop any of the following symptoms during treatment with SPRYCEL:

- chest pain
- feeling like your heart is beating too fast or you feel abnormal heartbeats
- vision changes that may last for a short time
- slurred speech
- shortness of breath

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Important Facts About SPRYCEL® (dasatinib) *(continued)*

Serious side effects (continued)

- **Pulmonary Arterial Hypertension (PAH):** SPRYCEL may cause high blood pressure in the vessels of your lungs. PAH may happen at any time 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 any of these symptoms:
 - shortness of breath
 - tiredness
 - swelling all over your body (fluid retention)
- **Severe skin reactions:** SPRYCEL may cause skin reactions that can sometimes be severe. Get medical help right away if you have any of these symptoms:
 - skin reaction with fever
 - sore mouth or throat
 - blistering or peeling of your skin or in the mouth
- **Tumor Lysis Syndrome (TLS):** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure and the need for dialysis treatment, as well as an abnormal heartbeat. Your healthcare provider may do blood tests to check you for TLS. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with SPRYCEL:
 - nausea
 - vomiting
 - weakness
 - swelling
 - shortness of breath
 - muscle cramps
 - seizures
- **Slowing of growth and development in children:** Effects on bone growth and development in children have happened with SPRYCEL and can sometimes be severe. Your healthcare provider will monitor your child's bone growth and development during treatment with SPRYCEL. Get medical help right away if your child develops bone pain.
- **Liver problems:** SPRYCEL can cause liver problems. People who have had liver problems in the past may be at risk for getting liver problems with SPRYCEL. Your healthcare provider will monitor liver function as needed during the treatment with SPRYCEL. Call your healthcare provider or get medical help right away if you develop any symptoms of liver problems, including: stomach area (abdominal) pain, yellowing of your skin or white part of your eyes, loss of appetite, bleeding, bruising, or dark "tea-colored" urine.

Most common side effects

The most common side effects of SPRYCEL in adults and children receiving SPRYCEL alone include:

- diarrhea
- headache
- skin rash
- shortness of breath
- tiredness
- nausea
- muscle pain

The most common side effects of SPRYCEL in children receiving SPRYCEL with chemotherapy include:

- swelling, pain, and redness of the lining of your mouth, throat, stomach, and bowel (mucositis)
- low white blood cell counts with fever
- fever
- diarrhea
- nausea
- vomiting
- muscle pain
- stomach-area (abdominal) pain
- cough

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Important Facts About SPRYCEL® (dasatinib) *(continued)*

The most common side effects of SPRYCEL in children receiving SPRYCEL with chemotherapy include (continued):

- headache
- rash
- tiredness
- constipation
- abnormal heart rate
- high blood pressure (hypertension)
- swelling
- infections
- low blood pressure
- decreased appetite
- allergic reactions
- shortness of breath
- nosebleed
- numbness or tingling of your hands and feet
- feeling confused or disoriented

SPRYCEL may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of SPRYCEL. **Tell your healthcare provider** if you have any side effect that bothers you or that does not go away.



Call your healthcare provider for medical advice about side effects.

You may report side effects to the FDA by calling 1-800-FDA-1088.

How do I store SPRYCEL® (dasatinib)?

SPRYCEL tablets should be stored 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.

Wear latex or nitrile gloves when handling tablets that have accidentally been crushed or broken.

Females who are pregnant should not handle crushed or broken SPRYCEL tablets.

Keep SPRYCEL and all medicines out of the reach of children.



This document has summarized the most important safety information for SPRYCEL. For more in-depth safety information, please read the Patient Information in the full [Prescribing Information](#).

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