

SPRYCEL®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using SPRYCEL?

SPRYCEL contains the active ingredient dasatinib. SPRYCEL is used to treat adults and children ages 12 months and older with chronic myeloid leukaemia (CML). It is also used to treat adults and children ages 12 months and older who have a particular form of acute lymphoblastic leukaemia (ALL) called Philadelphia chromosome positive or Ph+ ALL.

For more information, see Section [1. Why am I using SPRYCEL?](#) in the full CMI.

2. What should I know before I use SPRYCEL?

Do not use if you have ever had an allergic reaction to dasatinib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use SPRYCEL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SPRYCEL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use SPRYCEL?

- Your doctor will decide the dose that is most appropriate for you.
- Please follow your doctor's instructions about how and when to take SPRYCEL.

More instructions can be found in Section [4. How do I use SPRYCEL?](#) in the full CMI.

5. What should I know while using SPRYCEL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, nurse or pharmacist you visit
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	<p>that you are using SPRYCEL.</p> <ul style="list-style-type: none"> ● Have any tests recommended by your doctor done as soon as possible.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not give SPRYCEL to anyone else, even if they have the same condition as you or your child. ● Do not stop taking SPRYCEL, or lower the dosage, without checking with your doctor. ● Do not stop taking SPRYCEL tablets because you or your child are feeling better unless advised to do so by your doctor. ● Do not take SPRYCEL with grapefruit or grapefruit juice.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● SPRYCEL has been known to cause dizziness or light-headedness in some people. Make sure that you know how

	<p>you or your child may react to SPRYCEL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.</p>
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> • Store it in a cool dry place away from moisture, heat or sunlight. • Keep the pack in a cool dry place where the temperature stays below 30°C. • Keep this medicine out of the sight and reach of children.

For more information, see Section [5. What should I know while using SPRYCEL?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment. Sometimes they may be serious and you may require medical attention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

SPRYCEL[®] (s pry-sell)

Active ingredient: *dasatinib* (duh-sat-in-ib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using SPRYCEL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SPRYCEL.**

Where to find information in this leaflet:

- [1. Why am I using SPRYCEL?](#)
- [2. What should I know before I use SPRYCEL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SPRYCEL?](#)
- [5. What should I know while using SPRYCEL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using SPRYCEL?

SPRYCEL contains the active ingredient dasatinib. SPRYCEL acts by inhibiting the activity of proteins within the leukaemia cells of patients with CML or Ph+ ALL. These proteins are responsible for the uncontrolled growth of the leukaemia cells. By inhibiting these proteins, SPRYCEL kills the leukaemia cells in the

bone marrow and allows normal red cell, white cell and platelet production to resume.

SPRYCEL is used to treat adults and children ages 12 months and older with chronic myeloid leukaemia (CML). It is also used to treat adults and children ages 12 months and older who have a particular form of acute lymphoblastic leukaemia (ALL) called Philadelphia chromosome positive or Ph+ ALL.

Leukaemia is a cancer of immature white blood cells, which grow in the bone marrow. Under normal circumstances, as these white blood cells mature, they enter the blood stream where they fight infection and maintain the body's immune system. In leukaemia, these immature white blood cells multiply in an uncontrolled manner, occupying the bone marrow space and spilling out into the bloodstream. As a consequence, the production of normal red blood cells (oxygen carrying cells), white blood cells (cells which fight infection), and platelets (cells which help blood to clot) is compromised. Therefore patients with leukaemia are at risk of developing serious anaemia, infections and bleeding.

It is intended that SPRYCEL be used in adults with:

- Newly diagnosed Ph+ CML in the chronic phase who have not received any prior therapies, OR
- Ph+ CML across all phases who are no longer benefiting from other therapies for these diseases (resistance) or in patients who experience severe side effects to other therapies (intolerance), OR

- Newly diagnosed Ph+ ALL who have not received any prior therapies, OR
- Ph+ ALL who are no longer benefiting from other therapies for these diseases (resistance) or in patients who experience severe side effects to other therapies (intolerance).

It is intended that SPRYCEL be used in children with:

- Newly diagnosed Ph+ CML in the chronic phase who have not received any prior therapies, OR
- Ph+ CML in the chronic phase who are no longer benefiting from other therapies for these diseases (resistance) or in patients who experience severe side effects to other therapies (intolerance), OR
- Newly diagnosed Ph+ ALL who have not received any prior therapies.

There is no experience with SPRYCEL treatment in children under 1 year of age.

Ask your doctor if you have any questions about why SPRYCEL was prescribed for you or your child.

2. What should I know before I use SPRYCEL?

Warnings

Do not use SPRYCEL if:

- You or your child are allergic to dasatinib, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- If the expiry date printed on the pack has passed. If you or your child takes this medicine after the expiry date has passed, it may not work as well.
- The packaging is torn or shows signs of tampering.

Check with your doctor if you or your child:

- have any other medical conditions, especially the following: problems with your immune system, liver problem, heart problem, lactose intolerant, hepatitis B infection

If you have not told your doctor about any of the above, tell them before you or your child take SPRYCEL.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take SPRYCEL if you are a pregnant woman or intend to become pregnant.

SPRYCEL can cause harm to the unborn baby if it is given to a pregnant woman.

Tell your doctor if you are a sexually active man.

Men who take SPRYCEL are advised to use a condom to avoid pregnancy in their partner.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Women who are taking SPRYCEL should not breast-feed.

Where to get further information

Your doctor is the best person to answer any further questions you may have about SPRYCEL.

Anything your doctor tells you about SPRYCEL should be followed even if it is different from what is in this leaflet.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by SPRYCEL or they may affect how well SPRYCEL works.

Tell your doctor if you or your child are taking:

- ketoconazole, itraconazole, ritonavir, atazanavir, erythromycin, clarithromycin and grapefruit juice may all increase the level of SPRYCEL in your bloodstream.
- dexamethasone, phenytoin, carbamazepine, rifampicin, and phenobarbitone may all decrease the levels of SPRYCEL in your bloodstream.

- SPRYCEL may alter the blood levels of cyclosporin.
- Blood thinning medicines such as warfarin sodium, aspirin or non steroidal anti-inflammatory drugs (NSAIDs) taken with SPRYCEL may increase the risk of unwanted bleeding.
- Oral diabetes medicines from the glitazone family of drugs may interact with SPRYCEL.

You or your child should avoid taking cimetidine, famotidine, ranitidine or omeprazole while taking SPRYCEL as they all reduce stomach acid, which is necessary for the absorption of SPRYCEL.

Medicines that neutralise stomach acid (**antacids**), such as aluminium hydroxide, magnesium hydroxide or calcium carbonate **may be taken up to 2 hours before or 2 hours after SPRYCEL.**

Some medicines may be affected by SPRYCEL, or may affect how well it works. You or your child may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking SPRYCEL.

Know the medicines you take.

Keep a list of you or your child's medicines to show your doctor or pharmacist.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SPRYCEL.

4. How do I use SPRYCEL?

How much to take

- The usual starting dose for adults is 100 mg once daily (either as one 100 mg tablet or two 50 mg tablets). The entire dose of 100 mg is to be taken at one time either in the morning or the evening.
- Some adult patients may require an alternative starting dose (140 mg daily taken as two 70 mg tablets). The entire dose of 140 mg is to be taken at one time either in the morning or the evening.
- The starting dose for children is determined by body weight. The entire dose prescribed by your doctor should be taken at one time either in the morning or the evening.
- Your doctor will decide the dose that is most appropriate for you. Please follow your doctor's instructions about how and when to take SPRYCEL.

When to take SPRYCEL

- You or your child should take SPRYCEL consistently at the same time each day (either in the morning or in the evening), with or without a meal, as instructed by your doctor.

How to take SPRYCEL

- Swallow your SPRYCEL tablet(s) whole with a glass of water. Do not break, cut, chew or crush the tablet.

- Do not take SPRYCEL with grapefruit or grapefruit juice.

How long to take SPRYCEL

You or your child should not stop taking SPRYCEL, or reduce the dose without first talking to your doctor. Depending on you or your child's response and any side effects that may be experienced, your doctor may adjust the dose of SPRYCEL, upward or downward, or may temporarily discontinue the medicine.

If you forget to use SPRYCEL

If you miss a dose of SPRYCEL, take the next scheduled dose at its regular time. Don't make up for a missed dose by doubling up on tablets. Call your doctor or pharmacist if you are not sure what to do.

If you use too much SPRYCEL

If you think that you have used too much SPRYCEL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using SPRYCEL?

Things you should do

- **If you or your child are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SPRYCEL.**
- **Have any tests recommended by your doctor done as soon as possible.** Your doctor may order routine laboratory tests to evaluate your blood counts to see how well SPRYCEL is working.

Call your doctor straight away if you or your child:

- **become pregnant while taking SPRYCEL**
- **experience bleeding or easy bruising, no matter how mild**
- **develop a fever while taking SPRYCEL**
- **experience shortness of breath and fatigue while taking SPRYCEL**

Remind any doctor, dentist or pharmacist you visit that you are using SPRYCEL.

Things you should not do

- **Do not give SPRYCEL to anyone else, even if they have the same condition as you or your child.**

- **Do not stop taking SPRYCEL, or lower the dosage, without checking with your doctor.**
- **Do not stop taking SPRYCEL tablets because you or your child are feeling better unless advised to do so by your doctor.**

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SPRYCEL affects you.

SPRYCEL has been known to cause dizziness or light-headedness in some people. Make sure that you know how you or your child react to SPRYCEL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Looking after your medicine

- **Keep SPRYCEL tablets in the pack until it is time to take them.** If you or your child take the tablets out of the bottle they may not keep well.
- Keep the pack in a cool dry place where the temperature stays below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep this medicine out of the sight and reach of children.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">● swelling, weight gain, shortness of breath or chest pain● swelling around your eyes● skin infection - folliculitis, herpes● shortness of breath and fatigue● dark coloured urine, yellowing of your skin	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<p>and eyes, nausea, loss of appetite, light-coloured bowel movements</p> <ul style="list-style-type: none"> ● changes in the way your heart beats, for example - if you notice it beating faster ● bleeding - for example from: gastrointestinal tract; eye; nose; gums; serious bruising or excessive menstrual bleeding ● infections - urinary tract; eye infection; difficulty breathing; coughing ● fever ● painful rash with blisters ● a reduction in red blood cells, which may result in fatigue or dizziness ● a reduction in white blood cells, which are used to fight infection ● a reduction in cells that help your blood to clot after injury 	

Other side effects

Common side effects	What to do
<ul style="list-style-type: none">● headache; dizziness; numbness or tingling in arms, legs, fingers or toes; altered taste● diarrhoea, nausea, vomiting● shortness of breath, cough, accumulation of fluid in or around the lungs, pneumonia, chest pain● infection, fever● abdominal pain, bloating, flatulence, constipation, indigestion● high blood pressure● mouth ulcers● skin rash, dermatitis (including eczema), dry skin, itching or peeling skin, flushing● hair loss● visual disturbances: blurry or diminished vision, dry eye● fatigue	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Common side effects	What to do
<ul style="list-style-type: none"> ● swelling of the liver, abdomen, hands, lower legs, feet or face ● back pain, bone pain, joint pain, pain in fingers or toes, muscle aches or spasm, muscle weakness ● weight decrease, appetite disturbance ● gout ● conjunctivitis ● tinnitus (ringing in the ears) ● accumulation of fluid, foamy urine, weight gain (also known as nephrotic syndrome) 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What SPRYCEL contains

Active ingredient (main ingredient)	dasatinib
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">● lactose monohydrate● microcrystalline cellulose● hypromellose● croscarmellose sodium● magnesium stearate● Opadry White YS-1-18177-A
Potential allergens	lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What SPRYCEL looks like

SPRYCEL 20 mg tablet

White to off-white, biconvex, round tablet with "BMS" debossed on one side and "527" on the other

SPRYCEL 50 mg tablet

White to off-white, biconvex, oval tablet with "BMS" debossed on one side and "528" on the other

SPRYCEL 70 mg tablet

White to off-white, biconvex, round tablet with "BMS" debossed on one side and "524" on the other

SPRYCEL 100 mg tablet

White to off-white, biconvex, oval film-coated tablet with "BMS 100" debossed on one side and "852" on the other

Registration numbers

AUST R 125557 - 20 mg tablet - 60 tablets per bottle

AUST R 125559 - 50 mg tablet - 60 tablets per bottle

AUST R 125561 - 70 mg tablet - 60 tablets per bottle

AUST R 157352 - 100 mg tablet - 30 tablets per bottle

AUST R 125558 - 20 mg tablet - 60 tablets per blister pack (not marketed)

AUST R 125560 - 50 mg tablet - 60 tablets per blister pack (not marketed)

AUST R 125562 - 70 mg tablet - 60 tablets per blister pack (not marketed)

AUST R 157356 - 100 mg tablet - 30 tablets per blister pack (not marketed)

Who distributes SPRYCEL

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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