

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SPRYCEL®. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SPRYCEL against the benefits that are expected. This leaflet does not contain everything about SPRYCEL. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What SPRYCEL is used for

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.

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

How SPRYCEL works

The active ingredient in SPRYCEL is dasatinib. Dasatinib 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.

Before you take SPRYCEL

When you must not take SPRYCEL:

- **You or your child must not take SPRYCEL if you have a history of severe allergic reactions to SPRYCEL or to any of the ingredients listed at the end of this leaflet.**
- **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.
- **Do not take SPRYCEL after the expiry date printed on the pack.** If you or your child takes this medicine after the expiry date has passed, it may not work as well.
- **Do not take SPRYCEL if the packaging is torn or shows signs of tampering.**

Before you start to take SPRYCEL

Tell your doctor if you or your child have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

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

Women who are taking SPRYCEL should not breast-feed.

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 or your child have or have had any 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.

Taking other medicines

It is especially important to tell your doctor if you or your child are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may be affected by SPRYCEL or they may affect how well SPRYCEL works.

Tell your doctor if you or your child are taking:

- Nizoral® (ketoconazole), Sporanox® (itraconazole), Norvir® (ritonavir), Reyataz® (atazanavir), E-Mycin® (erythromycin), Klacid® (clarithromycin) and grapefruit juice may all increase the level of SPRYCEL in your bloodstream.
- Maxidex® (dexamethasone), Dilantin® (phenytoin), Tegretol® (carbamazepine), Rifadin® (rifampicin), and Phenobarbitone tablets may all decrease the levels of SPRYCEL in your bloodstream.
- SPRYCEL may alter the blood levels of Sandimmun® (cyclosporin).
- Blood thinning medicines such as Coumadin® (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 Tagamet® (cimetidine), Pepcidine® (famotidine), Zantac® (ranitidine) or Probitor® (omeprazole) while taking SPRYCEL as they all reduce stomach acid, which is necessary for the absorption of SPRYCEL.

Medicines that neutralise stomach acid, such as Mylanta® (aluminium hydroxide/magnesium hydroxide), Andrews Tums Antacid® (calcium carbonate) or Mylanta® (calcium carbonate and magnesium hydroxide) 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.

How to take SPRYCEL

How much to take:

You or your child should take your tablets consistently either in the morning or in the evening.

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.

How to take it:

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.

When to take it:

Try to take your dose of SPRYCEL at the same time each day, with or without a meal, as instructed by your doctor.

How long to take it:

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 take it:

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 take too much (overdose):

Immediately telephone your doctor or Poisons Information Centre (telephone: 131126) or go to the Accident and Emergency Department at your nearest hospital, if you, your child or anyone else may have taken too much SPRYCEL. Do this even if there are no signs of discomfort or poisoning.

While you are taking SPRYCEL

Things you must do:

- **You must tell your doctor immediately if you or your child become pregnant while taking SPRYCEL.**
- **Tell all of the doctors, dentists and pharmacists who are treating you or your child that you are taking SPRYCEL.**
- **If you or your child are about to be started on any new medicine, tell your doctor and pharmacist that you are taking SPRYCEL.**
- **Tell your doctor immediately if you or your child experience bleeding or easy bruising, no matter how mild.**
- **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.

- **Notify your doctor immediately if you or your child develop a fever while taking SPRYCEL.**
- **Tell your doctor immediately if you or your child experience shortness of breath and fatigue while taking SPRYCEL**

Things you must not do:

- **Do not give SPRYCEL to anyone else, even if they have the same condition as you or your child.**
- **Do not use SPRYCEL to treat any other complaints unless your doctor tells you to.**
- **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.**

Things to be careful of:

- **Be careful driving or operating machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while you are taking SPRYCEL.

Like all medicines, it is possible that SPRYCEL may have unwanted side effects in some people. There are many side effects caused by medicines used to treat leukaemia. During treatment with SPRYCEL you or your child will require close medical supervision.

The more common side effects of SPRYCEL are:

- 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
- 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 immediately if you notice any of the following:

- 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 or yellowing of your skin and eyes

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- 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

The use of SPRYCEL is also associated with a reduction in certain types of blood cells in the body:

- 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

These are serious side effects. If you or your child have them you may need urgent medical attention.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you or your child feel unwell.

Product Description:

What it 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

Ingredients

Active Ingredient:

dasatinib

Inactive Ingredients:

lactose monohydrate, microcrystalline cellulose, hypromellose, croscarmellose sodium, magnesium stearate and Opadry White YS-1-18177-A.

Storage

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.

Do not store SPRYCEL or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

Sponsored by

Bristol-Myers Squibb Australia Pty Ltd
4 Nexus Court, Mulgrave
Victoria 3170, Australia

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

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.

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