

Dasatinib Sandoz[®]

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 Dasatinib Sandoz?

Dasatinib Sandoz contains the active ingredient dasatinib. Dasatinib Sandoz is used to treat chronic myeloid leukaemia (CML) and a particular form of acute lymphoblastic leukaemia (ALL) called Philadelphia chromosome positive (Ph+ ALL).

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

2. What should I know before I use Dasatinib Sandoz?

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 Dasatinib Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dasatinib Sandoz 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 Dasatinib Sandoz?

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

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

5. What should I know while using Dasatinib Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking Dasatinib Sandoz.• Call your doctor straight away if you or your child:<ul style="list-style-type: none">• become pregnant while taking Dasatinib Sandoz.• experience bleeding or easy bruising, no matter how mild.• develop a fever while taking Dasatinib Sandoz.• experience shortness of breath and fatigue while taking Dasatinib Sandoz
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor.• Do not give Dasatinib Sandoz to anyone else, even if they have the same condition as you or your child. Do not use Dasatinib Sandoz to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Dasatinib Sandoz affects you. Dasatinib Sandoz has been known to cause dizziness or light-headedness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them. If you take the tablets out of the bottle or blister pack they may not keep well.• Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C. Contains sugars as Lactose.

For more information, see Section [5. What should I know while using Dasatinib Sandoz?](#) 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.

Dasatinib Sandoz®

Active ingredient(s): *dasatinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dasatinib Sandoz. **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 Dasatinib Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Dasatinib Sandoz?

Dasatinib Sandoz contains the active ingredient **dasatinib**. Dasatinib Sandoz is used to treat **chronic myeloid leukaemia (CML)** and a particular form of **acute lymphoblastic leukaemia (ALL)** called **Philadelphia chromosome positive (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.

Dasatinib Sandoz 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, Dasatinib Sandoz kills the leukaemia cells in the bone marrow and allows normal red cell, white cell and platelet production to resume.

Dasatinib Sandoz is used to treat adults and children ages 12 months and older with CML or Ph+ ALL.

It is intended that Dasatinib Sandoz 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 Dasatinib Sandoz 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 dasatinib treatment in children under 1 year of age.

2. What should I know before I use Dasatinib Sandoz?

Warnings

Do not use Dasatinib Sandoz if:

- you 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.
- Do not take Dasatinib Sandoz if you are pregnant or intend to become pregnant.** Dasatinib Sandoz can cause harm to the unborn baby if it is given to a pregnant woman.

Check with your doctor if you:

- have any other medical conditions including:
 - problems with your immune system
 - liver problem
 - heart problem
 - lactose intolerant
 - hepatitis B infection
- take any medicines for any other condition.

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

Tell your doctor if you are pregnant or intend to become pregnant. You cannot take Dasatinib Sandoz if you are

pregnant or intend to become pregnant. Dasatinib Sandoz can cause harm to the unborn baby if it is given to a pregnant woman.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Women who are taking Dasatinib Sandoz should not breastfeed.

Tell your doctor if you are a sexually active man. Men who take Dasatinib Sandoz are advised to use a condom to avoid pregnancy in their partner.

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 Dasatinib Sandoz or they may affect how well Dasatinib Sandoz works.

Tell your doctor if you are taking:

- ketoconazole, itraconazole, ritonavir, atazanavir, erythromycin, clarithromycin and grapefruit juice may all increase the level of Dasatinib Sandoz in your bloodstream.
- dexamethasone, phenytoin, carbamazepine, rifampicin, and Phenobarbitone may all decrease the levels of Dasatinib Sandoz in your bloodstream.
- Dasatinib Sandoz may alter the blood levels of cyclosporin.
- Blood thinning medicines such as warfarin sodium, aspirin or non steroidal anti-inflammatory drugs (NSAIDs) taken with Dasatinib Sandoz may increase the risk of unwanted bleeding.
- Oral diabetes medicines from the glitazone family of drugs may interact with Dasatinib Sandoz.

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

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 Dasatinib Sandoz.

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

4. How do I use Dasatinib Sandoz?

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.
- Follow the instructions provided and use Dasatinib Sandoz until your doctor tells you to stop

How to take Dasatinib Sandoz

- Swallow your Dasatinib Sandoz tablet(s) whole with a glass of water. Do not break, cut, chew or crush the tablet.
- Do not take Dasatinib Sandoz with grapefruit, or grapefruit juice.

When to take Dasatinib Sandoz

Dasatinib Sandoz should be taken consistently either in the morning or in the evening. With or without a meal, as instructed by your doctor.

How long to take Dasatinib Sandoz

You or your child should not stop taking Dasatinib Sandoz, 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 Dasatinib Sandoz, upward or downward, or may temporarily discontinue the medicine.

If you forget to use Dasatinib Sandoz

Dasatinib Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, take your next scheduled dose at its regular time.

Do not take a double dose to make up for the dose you missed.

Call your doctor or pharmacist if you are not sure what to do.

If you use too much Dasatinib Sandoz

If you think that you have used too much Dasatinib Sandoz, 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 Dasatinib Sandoz?

Things you should do

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 Dasatinib Sandoz is working.

Call your doctor straight away if you:

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

Remind any doctor, dentist or pharmacist you visit that you or your child are using Dasatinib Sandoz.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage, without checking with your doctor.
- Do not give Dasatinib Sandoz to anyone else, even if they have the same condition as you or your child.
- Do not use Dasatinib Sandoz to treat any other complaints unless your doctor tells you to.

Driving or using machines

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

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

Looking after your medicine

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

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

Keep it where young children cannot reach it.

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 or if the packaging is torn or shows signs of tampering.

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.

Less serious side effects

Less serious 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• 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)	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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 or yellowing of your skin and eyes, nausea, loss of appetite, light-coloured bowel movements• 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	<p>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.</p>

<ul style="list-style-type: none"> 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 	
---	--

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 Dasatinib Sandoz contains

Active ingredient (main ingredient)	dasatinib
Other ingredients (inactive ingredients)	Tablet core: Lactose monohydrate, microcrystalline cellulose, hypromellose, croscarmellose sodium, and magnesium stearate. Film coating: Titanium dioxide, hypromellose and triethyl citrate.
Potential allergens	Lactose monohydrate

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

What Dasatinib Sandoz looks like

Dasatinib Sandoz 20 mg tablet

White to off-white, round, biconvex, film-coated tablet debossed with DAS on one side and 20 on the other side. (AUST R 335111)

Dasatinib Sandoz 50 mg tablet

White to off-white, oval, biconvex, film-coated tablet debossed with DAS on one side and 50 on the other side. (AUST R 335106)

Dasatinib Sandoz 70 mg tablet

White to off-white, round, biconvex, film-coated tablet debossed with DAS on one side and 70 on the other side. (AUST R 335110)

Dasatinib Sandoz 100 mg tablet

White to off-white, oval, biconvex, film-coated tablet debossed with DAS on one side and 100 on the other side. (AUST R 335109).

Who distributes Dasatinib Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

This leaflet was prepared in December 2024.

® Registered Trade Mark. The trade marks mentioned in this material are the property of their respective owners.