

# Dasatinib Dr.Reddy's

## 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 Dr.Reddy's?

Dasatinib Dr.Reddy's contains the active ingredient dasatinib. Dasatinib Dr.Reddy's is used for the treatment of chronic myeloid leukaemia (CML). It is also used to treat 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 Dasatinib Dr.Reddy's?](#) in the full CMI.

### 2. What should I know before I use Dasatinib Dr.Reddy's?

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 Dr.Reddy's?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Dasatinib Dr.Reddy's 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 Dr.Reddy's?

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

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

### 5. What should I know while using Dasatinib Dr.Reddy's?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Tell all doctors, dentists and pharmacists who are treating you that you are taking Dasatinib Dr.Reddy's.</li><li>Tell your doctor if you become pregnant while taking Dasatinib Dr.Reddy's.</li><li>Tell your doctor immediately if you or your child experience bleeding or easy bruising, no matter how mild.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not give Dasatinib Dr.Reddy's to anyone else, even if they have the same condition as you or your child.</li><li>Do not use Dasatinib Dr.Reddy's to treat any other complaints unless your doctor tells you to.</li><li>Do not stop taking Dasatinib Dr.Reddy's, or lower the dosage, without checking with your doctor.</li><li>Do not stop taking Dasatinib Dr.Reddy's tablets because you or your child are feeling better unless advised to do so by your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful driving or operating machinery until you know how Dasatinib Dr.Reddy's affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Keep Dasatinib Dr.Reddy's where young children cannot reach it.</li><li>Keep your tablets in their container until it is time to take them.</li><li>Keep Dasatinib Dr.Reddy's in a cool dry place where the temperature stays below 30°C.</li><li>A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines. Do not store this medicine or any other medicine in the bathroom or near a sink.</li><li>Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines</li></ul>

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

### 6. Are there any side effects?

Tell your doctor immediately or go to your nearest hospital if you experience 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, or

painful rash with blisters.

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 Dr.Reddy's

Active ingredient: *dasatinib*

## Consumer Medicine Information (CMI)

This leaflet provides important information about Dasatinib Dr.Reddy's. 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 Dr.Reddy's.

### Where to find information in this leaflet:

1. Why am I using Dasatinib Dr.Reddy's?
2. What should I know before I use Dasatinib Dr.Reddy's?
3. What if I am taking other medicines?
4. How do I use Dasatinib Dr.Reddy's?
5. What should I know while using Dasatinib Dr.Reddy's?
6. Are there any side effects?
7. Product details

## 1. Why am I using Dasatinib Dr.Reddy's?

Dasatinib Dr.Reddy's is used to treat adults and children with chronic myeloid leukaemia (CML). It is also used to treat adults and children 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 Dasatinib Dr.Reddy's be used in adults with:

- newly diagnosed Ph+ CML in the chronic phase.
- chronic, accelerated or myeloid or lymphoid blast phase CML with resistance to prior therapy.
- newly diagnosed Ph+ acute lymphoblastic leukaemia integrated with chemotherapy.
- Ph+ acute lymphoblastic leukaemia with resistance or intolerance to prior therapy.

It is intended that Dasatinib Dr.Reddy's be used in children with:

- Ph+ CML in the chronic phase.
- newly diagnosed Ph+ ALL in combination with chemotherapy.

There is no experience with Dasatinib Dr.Reddy's treatment in children under 1 year of age.

Ask your doctor if you have any questions about why Dasatinib Dr.Reddy's was prescribed for you.

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

### How Dasatinib Dr.Reddy's Works

The active ingredient in Dasatinib Dr.Reddy's 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, Dasatinib Dr.Reddy's kills the leukaemia cells in the bone marrow and allows normal red cell, white cell and platelet production to resume.

## 2. What Should I know before I Use Dasatinib Dr.Reddy's?

### When you must not take Dasatinib Dr.Reddy's:

- **You or your child must not take Dasatinib Dr.Reddy's if you have a history of severe allergic reactions to Dasatinib Dr.Reddy's or to any of the ingredients listed at the end of this leaflet.**
- **Do not take Dasatinib Dr.Reddy's if you are pregnant or intend to become pregnant.**

Dasatinib Dr.Reddy's can cause harm to the unborn baby if it is given to a pregnant woman.

- **Do not take Dasatinib Dr.Reddy's after the expiry date printed on the pack.**

If you or your child take this medicine after the expiry date has passed, it may not work as well.

- **Do not take Dasatinib Dr.Reddy's if the packaging is torn or shows signs of tampering.**

### Before you start to take Dasatinib Dr.Reddy's

Tell your doctor if you 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 Dasatinib Dr.Reddy's should not breast-feed.

**Tell your doctor if you are sexually active.**

Sexually active male or female patients of child bearing potential taking dasatinib should use adequate contraception.

**Tell your doctor if you 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 Dasatinib Dr.Reddy's.**

### 3. What if I am taking other medicines?

**Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with Dasatinib Dr.Reddy's. These medicines include:

- Nizoral® (ketoconazole), Sporanox® (itraconazole), Norvir® (ritonavir), Reyataz® (atazanavir), E-Mycin® (erythromycin), Klacid® (clarithromycin) and grapefruit juice may all increase the level of Dasatinib Dr.Reddy's in your bloodstream.
- Maxidex® (dexamethasone), Dilantin® (phenytoin), Tegretol® (carbamazepine), Rifadin® (rifampicin), and Phenobarbitone tablets may all decrease the levels of Dasatinib Dr.Reddy's in your bloodstream.

Dasatinib Dr.Reddy's 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 Dasatinib Dr.Reddy's may increase the risk of unwanted bleeding.
- Oral diabetes medicines from the glitazone family of drugs may interact with Dasatinib Dr.Reddy's.

You or your child should avoid taking Tagamet® (cimetidine), Pepcidine® (famotidine), Zantac® (ranitidine) or Probitor® (omeprazole) while taking Dasatinib Dr.Reddy's as they all reduce stomach acid, which is

necessary for the absorption of Dasatinib Dr.Reddy's. 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 Dasatinib Dr.Reddy's. Some medicines may be affected by Dasatinib Dr.Reddy's, 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 Dasatinib Dr.Reddy's.

**Know the medicines you take.**

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

These medicines may be affected by Dasatinib Dr.Reddy's or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dasatinib Dr.Reddy's.

### 4. How do I use Dasatinib Dr.Reddy's?

**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 Dasatinib Dr.Reddy's.

**How to take it:**

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

**When to take it:**

Try to take your dose of Dasatinib Dr.Reddy's at the same time each day, consistently either in the morning or in the evening, with or without a meal, as instructed by your

doctor.

### How long to take it:

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

### If you forget to take it:

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

### If you use too much Dasatinib Dr.Reddy's

If you think that you have used too much Dasatinib Dr.Reddy's, 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.

### Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

## 5. What should I know while using Dasatinib Dr.Reddy's?

### Things you should do

- **You must tell your doctor immediately if you or your child become pregnant while taking Dasatinib Dr.Reddy's.**
- **Tell all of the doctors, dentists and pharmacists who are treating you or your child that you are taking Dasatinib Dr.Reddy's.**
- **If you or your child are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Dasatinib Dr.Reddy's.**
- **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 Dasatinib Dr.Reddy's is working.

- **Notify your doctor immediately if you or your child develop a fever while taking Dasatinib Dr.Reddy's.**
- **Tell your doctor immediately if you or your child experience shortness of breath and fatigue while taking Dasatinib Dr.Reddy's**

### Things you should not do

- **Do not give Dasatinib Dr.Reddy's to anyone else, even if they have the same condition as you or your child.**
- **Do not use Dasatinib Dr.Reddy's to treat any other complaints unless your doctor tells you to.**
- **Do not stop taking Dasatinib Dr.Reddy's, or lower the dosage, without checking with your doctor.**
- **Do not stop taking Dasatinib Dr.Reddy's tablets because you or your child are feeling better unless advised to do so by your doctor.**

### Driving or using machines

- **Be careful driving or operating machinery until you know how Dasatinib Dr.Reddy's affects you.**

Dasatinib Dr.Reddy's 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 Dr.Reddy's 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 their container until it is time to take them.
- If you take the tablets out of their container they may not keep well.
- Keep Dasatinib Dr.Reddy's in a cool dry place where the temperature stays below 30°C.
- Keep Dasatinib Dr.Reddy's where young children cannot reach it.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not store it:

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

Heat and dampness can destroy some medicines.

**Getting rid of any unwanted medicine**  
If your doctor tells you to stop taking Dasatinib Dr.Reddy's, or the medication has passed its expiry date, ask your pharmacist what to do with any tablets that are left over.

## 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Dasatinib Dr.Reddy's.

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

Ask your doctor or pharmacist to answer any questions you may have.

### Less serious side effects

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

<ul style="list-style-type: none"> <li>• headache; dizziness; numbness or tingling in arms, legs, fingers or toes; altered taste</li> <li>• diarrhoea, nausea, vomiting</li> <li>• shortness of breath, cough, accumulation of fluid in or around the lungs, pneumonia, chest pain</li> <li>• infection, fever</li> <li>• abdominal pain, bloating, flatulence, constipation, indigestion</li> <li>• high blood pressure</li> <li>• mouth ulcers</li> <li>• skin rash, dermatitis (including eczema), dry skin, itching or peeling skin, flushing</li> <li>• hair loss</li> <li>• visual disturbances: blurry or diminished vision, dry eye</li> <li>• fatigue</li> <li>• swelling of the liver, abdomen, hands, lower legs, feet or face</li> <li>• back pain, bone pain, joint pain, pain in fingers or toes, muscle aches or spasm, muscle weakness</li> <li>• weight decrease, appetite disturbance</li> <li>• gout</li> <li>• conjunctivitis</li> <li>• tinnitus (ringing in the ears)</li> <li>• accumulation of fluid, foamy urine, weight gain (also known as nephrotic syndrome)</li> </ul>	<p><b>Speak to your doctor of you have any of these less serious side effects and they worry you.</b></p>
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### Serious side effects

**Tell your doctor immediately if you notice any of the following:**

These may be serious side-effects. Your doctor may interrupt your Dasatinib Dr.Reddy's treatment.

<ul style="list-style-type: none"> <li>• swelling, weight gain, shortness of breath or chest pain</li> <li>• swelling around your eyes</li> <li>• skin infection - folliculitis, herpes</li> <li>• shortness of breath and fatigue</li> <li>• dark coloured urine or yellowing of your skin and eyes</li> <li>• changes in the way your heart beats, for example - if you notice it beating faster</li> <li>• bleeding - for example from: gastrointestinal tract; eye; nose; gums; serious bruising or excessive menstrual bleeding</li> <li>• infections - urinary tract; eye infection; difficulty breathing; coughing</li> <li>• fever</li> <li>• painful rash with blisters</li> </ul> <p>The use of Dasatinib Dr.Reddy's is also associated with a reduction in certain types of blood cells in the body:</p> <ul style="list-style-type: none"> <li>• a reduction in red blood cells, which may result in fatigue or dizziness</li> <li>• a reduction in white blood cells, which are used to fight infection</li> <li>• a reduction in cells that help your blood to clot after injury.</li> </ul>	<p><b>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.</b></p>
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These may be very serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.**

**Ask your doctor or pharmacist if you don't understand anything in this list.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### 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](http://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 Dr.Reddy's contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• 20, 50, 70 or, 100 mg of dasatinib</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Hydrogenated castor oil,</li><li>• silicon dioxide,</li><li>• lactose,</li><li>• microcrystalline cellulose,</li><li>• croscarmellose sodium,</li><li>• magnesium stearate,</li><li>• hypromellose and</li><li>• titanium dioxide.</li></ul>
<b>Potential allergens</b>	lactose

Dasatinib Dr.Reddy's are gluten free.

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

### What Dasatinib Dr.Reddy's looks like

Dasatinib Dr.Reddy's 20 mg tablets are white to off-white, round tablet with "599" debossed on one side and plain on the other. [AUST R 337458]. Blister packs of 60 tablets.

Dasatinib Dr.Reddy's 50 mg tablets are white to off-white, oval tablet with "600" debossed on one side and plain on the other. [AUST R 337451]. Blister packs of 60 tablets.

Dasatinib Dr.Reddy's 70 mg tablets are white to off-white, round tablet with "601" debossed on one side and plain on the other. [AUST R 337456]. Blister packs of 60 tablets.

Dasatinib Dr.Reddy's 100 mg tablets are white to off-white, oval film-coated tablet with "603" debossed on one side and plain on the other. [AUST R 337460]. Blister packs of 30 tablets.

### Who distributes Dasatinib Dr.Reddy's

Dr Reddy's Laboratories (Australia) Pty Ltd  
Suite 3.03, Level 3, 390 St Kilda Road  
Melbourne, VIC, 3004  
Medical enquiries: 1800 733 397

In New Zealand Dasatinib Dr.Reddy's is distributed by:

Dr. Reddy's New Zealand Ltd  
82 Totara Crescent  
Lower Hutt 5011  
WELLINGTON

Tel: 0800 362 733

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