

# DASATINIB VIATRIS

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## 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.

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### 1. Why am I using DASATINIB VIATRIS?

DASATINIB VIATRIS contains the active ingredient dasatinib. DASATINIB VIATRIS is used to treat adults aged 18 years and older with:

- Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukaemia in the chronic phase.
- Chronic, accelerated or myeloid or lymphoid blast phase chronic myeloid leukaemia with resistance or intolerance to prior therapy including imatinib.
- Philadelphia chromosome positive acute lymphoblastic leukaemia with resistance or intolerance to prior therapy.

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

## **2. What should I know before I use DASATINIB VIATRIS?**

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 VIATRIS?](#) in the full CMI.

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

Some medicines may interfere with DASATINIB VIATRIS 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 VIATRIS?**

- 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 VIATRIS.

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

## 5. What should I know while using DASATINIB VIATRIS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>● Remind any doctor, dentist or pharmacist you visit that you are using DASATINIB VIATRIS.</li><li>● Have any tests recommended by your doctor done as soon as possible.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not give DASATINIB VIATRIS to anyone else, even if they have the same condition as you.</li><li>● Do not stop taking DASATINIB VIATRIS, or lower the dosage, without checking with your doctor.</li><li>● Do not stop taking DASATINIB VIATRIS tablets because you are feeling better unless advised to do so by your doctor.</li><li>● Do not take DASATINIB VIATRIS with grapefruit or grapefruit juice.</li></ul>

<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● DASATINIB VIATRIS has been known to cause dizziness or light-headedness in some people. Make sure that you know how you may react to DASATINIB VIATRIS before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.</li> </ul>
<p><b>Looking after your medicine</b></p>	<ul style="list-style-type: none"> <li>● Store it in a cool dry place away from moisture, heat or sunlight.</li> <li>● Keep the pack in a cool dry place where the temperature stays below 25°C.</li> <li>● Keep this medicine out of the sight and reach of children.</li> </ul>

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

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

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using DASATINIB VIATRIS. **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 VIATRIS.**

**Where to find information in this leaflet:**

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

## 1. Why am I using DASATINIB VIATRIS?

**DASATINIB VIATRIS contains the active ingredient dasatinib.** DASATINIB VIATRIS works 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 kills the leukaemia

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

**DASATINIB VIATRIS is used to treat adults aged 18 years or over with:**

- Newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukaemia in the chronic phase.
- Chronic, accelerated or myeloid or lymphoid blast phase chronic myeloid leukaemia with resistance or intolerance to prior therapy including imatinib.
- Philadelphia chromosome positive acute lymphoblastic leukaemia with resistance or intolerance to prior therapy.

It belongs to a group of medicines called protein-tyrosinekinase inhibitors.

## **2. What should I know before I use DASATINIB VIATRIS?**

### **Warnings**

**Do not use DASATINIB VIATRIS 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.
- The expiry date printed on the pack has passed
- The packaging is torn or shows signs of tampering.

**Do not give this medicine to a child under the age of 18 years.**

### **Check with your doctor if you:**

- have or have had any of the following medical conditions:
  - problems with your immune system
  - liver problem
  - heart problem
  - lactose intolerant
  - hepatitis B infection.
- are pregnant or plan to become pregnant or are breastfeeding. Women who are taking dasatinib should not breast-feed. (See section Pregnancy and breastfeeding)
- are a sexually active man. Men who take dasatinib are advised to use a condom to avoid pregnancy in their partner.
- have allergies to any other medicines, foods, preservatives or dyes
- have recently been vaccinated or plan to get a vaccination
- are planning to have surgery or an anaesthetic
- are currently receiving or are planning to receive dental treatment.



If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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 this medicine if you are pregnant or plan to become pregnant.**

DASATINIB VIATRIS 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 DASATINIB VIATRIS are advised to use a condom to avoid pregnancy in their partner.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.**

Women who are taking DASATINIB VIATRIS should not breast-feed.

## **Where to get further information**

Your doctor is the best person to answer any further questions you may have about DASATINIB VIATRIS. Anything your doctor tells you about DASATINIB VIATRIS 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 DASATINIB VIATRIS or they may affect how well DASATINIB VIATRIS works.**

Tell your doctor if you are taking:

- Medicines that may increase dasatinib level in your bloodstream, such as ketoconazole, itraconazole, erythromycin, clarithromycin, ritonavir, atazanavir, lopinavir, grapefruit juice.
- Medicines that may decrease dasatinib level in your bloodstream, such as dexamethasone, phenytoin, carbamazepine, rifampicin, phenobarbital and St John's wort.
- Dasatinib may alter the blood levels of ciclosporin.
- Medicines that reduce stomach acid, such as antacids and histamine-2 antagonists/proton pump inhibitors (famotidine and omeprazole).
- Medicines that may have their plasma concentration altered by dasatinib, such as simvastatin, astemizole, terfenadine, cisapride, pimozone, quinidine, bepridil or ergot alkaloids.
- Blood thinning medicines, such as warfarin, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs)

taken with dasatinib may increase the risk of unwanted bleeding.

- Oral diabetes medicines from the glitazone family of medicines may interact with dasatinib.
- Medicines that neutralise stomach acid, such as aluminium hydroxide, magnesium hydroxide, calcium carbonate and calcium carbonate/hydroxide. **These medicines may be taken up to 2 hours before or 2 hours after dasatinib.**

**Some medicines may interfere with DASATINIB VIATRIS and affect how it works.** You 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 VIATRIS.

**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 VIATRIS.**

## **4. How do I use DASATINIB VIATRIS?**

### **How much to take / use**

- Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.
- You should take your tablets consistently either in the morning or in the evening.
- The usual starting dose 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 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.
- Do not stop taking your medicine or change your dosage without first talking with your doctor. This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.
- Depending on your response and on any side effects that you may experience, your doctor may adjust your dose of DASATINIB VIATRIS, upward or downward, or may temporarily discontinue your medicine.

## **When to take DASATINIB VIATRIS**

- Take your medicine at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

## **How to take DASATINIB VIATRIS**

- Swallow the tablets whole with a full glass of water.
- Do not break, cut, chew or crush the tablet.
- Do not take DASATINIB VIATRIS with grapefruit or grapefruit juice.

## **If you forget to take DASATINIB VIATRIS**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you use too much DASATINIB VIATRIS**

If you think that you have used too much DASATINIB VIATRIS, 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 VIATRIS?**

### **Things you should do**

- Tell any other doctors, dentists, and pharmacists who treat you that you are taking DASATINIB VIATRIS.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking DASATINIB VIATRIS.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking DASATINIB VIATRIS.
- If you are about to have any blood tests, tell your doctor that you are taking DASATINIB VIATRIS.
- 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 VIATRIS is working.

## **Call your doctor straight away if you:**

- become pregnant or plan to breastfeed while taking DASATINIB VIATRIS
- experience bleeding or easy bruising, no matter how mild
- develop a fever while taking DASATINIB VIATRIS
- experience shortness of breath and fatigue while taking DASATINIB VIATRIS

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

## **Things you should not do**

- Do not give DASATINIB VIATRIS to anyone else, even if they have the same condition as you.
- Do not stop taking DASATINIB VIATRIS tablets or lower the dosage, because you are feeling better unless advised to do so by your doctor.
- Do not take DASATINIB VIATRIS 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 VIATRIS affects you.**

DASATINIB VIATRIS has been known to cause dizziness or lightheadedness in some people. Make sure that you know how you react to DASATINIB VIATRIS before you drive a car, operate machinery,

or do anything else that could be dangerous if you are dizzy.

## **Looking after your medicine**

- Keep DASATINIB VIATRIS 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.
- Keep the pack in a cool dry place where the temperature stays below 25°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 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.

## **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"><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, nausea, loss of appetite, light-coloured bowel movements</li><li>● changes in the way your heart</li><li>● beats, for example - if you notice it beating faster</li><li>● bleeding - for example from:<ul style="list-style-type: none"><li>● gastrointestinal tract;</li><li>● eye;</li><li>● nose; gums; serious bruising or</li></ul></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>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● excessive menstrual bleeding</li> <li>● infections - urinary tract; eye</li> <li>● infection; difficulty breathing;</li> <li>● coughing</li> <li>● fever</li> <li>● painful rash with blisters</li> <li>● a reduction in red blood cells,</li> <li>● which may result in fatigue or</li> <li>● dizziness</li> <li>● a reduction in white blood cells,</li> <li>● which are used to fight infection</li> <li>● a reduction in cells that help your blood to clot after injury</li> </ul>	

## Other side effects

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

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

**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](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 VIATRIS contains**

<b>Active ingredient (main ingredient)</b>	dasatinib
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• ethylcellulose</li></ul>

	<ul style="list-style-type: none"> <li>● lactose monohydrate</li> <li>● croscarmellose sodium</li> <li>● magnesium stearate</li> <li>● colloidal silicon dioxide</li> <li>● hypromellose</li> <li>● hyprolose</li> <li>● triethyl citrate</li> <li>● titanium dioxide</li> </ul>
<b>Potential allergens</b>	lactose monohydrate

This medicine contains sugars as lactose.

This medicine does not contain gluten.

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

## **What DASATINIB VIATRIS looks like**

Dasatinib 20 mg tablet

(blister: AUST R 290135, bottle: AUST R 290130)

White to off-white, round, biconvex coated tablet.

Engraved "APO" on one side, over "DA" over "20" on the other side.

Dasatinib 50 mg tablet

(blister: AUST R 290142, bottle: AUST R 290133)

White to off-white, oval, bevelled-edged, biconvex

coated tablet. Engraved "APO" on one side, "DAS50" on the other side.

Dasatinib 70 mg tablet

(blister: AUST R 290138, bottle: AUST R 290141)

White to off-white, round, biconvex coated tablet.  
Engraved "APO" on one side, "DA" over "70" on the other side.

Dasatinib 100 mg tablet

(blister: AUST R 290139, bottle: AUST R 290132)

White to off-white, oval, bevelled-edged, biconvex coated tablet. Engraved "APO" on one side, "DAS100" on the other side.

## **Who distributes DASATINIB VIATRIS**

### **Sponsor**

Helix Pharmaceuticals Pty Ltd

C/-EGA Corporate Advisers Pty Ltd

Level 12, 468 St Kilda Rd

Melbourne VIC 3004

Contact: [info@helixpharmaceuticals.com.au](mailto:info@helixpharmaceuticals.com.au)

### **Distributor**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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