

# TE-DASATINIB®

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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 TE-DASATINIB?

TE-DASATINIB contains the active ingredient dasatinib. TE-DASATINIB is used to treat adults and children ages 12 months and older with chronic myeloid leukaemia (CML).

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

### 2. What should I know before I use TE-DASATINIB?

Do not use if you have ever had an allergic reaction to TE-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 TE-DASATINIB?](#) in the full CMI.

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

Some medicines may interfere with TE-DASATINIB 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 TE-DASATINIB?

- Follow all directions given to you by your doctor or pharmacist carefully.
- 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.
- 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.

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

### 5. What should I know while using TE-DASATINIB?

Things you should do	
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- Remind any doctor, dentist, or pharmacist

	<p>you visit that you are using TE-DASATINIB.</p> <ul style="list-style-type: none"> <li>● If you become pregnant while you are being treated with this medicine, tell your doctor immediately.</li> <li>● Keep all your doctor's appointments so that your progress can be checked.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not stop using this medicine suddenly or start taking a lower dose without consulting your doctor.</li> <li>● Do not give this medication to anyone else, even if they have the same condition as you.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● This medicine has been known to cause dizziness or light-headedness in some patients. Make sure you know how TE-DASATINIB affects you before driving or operating machinery.</li> </ul>

### Looking after your medicine

- Store TE-DASATINIB in a cool dry place, out of direct light, where the temperature is below 25°C.
- Keep TE-DASATINIB in the original packaging, in a safe place, away from children.

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

## 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you or your child do not feel well while you are taking TE-DASATINIB, even if you do not think it is connected with the medicine. This medicine helps most people with chronic myeloid leukaemia (CML), however, like all medicines, TE-DASATINIB can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of these side effects.

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.

# TE-DASATINIB®

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

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using TE-DASATINIB. **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 TE-DASATINIB.**

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

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

## 1. Why am I using TE-DASATINIB?

**TE-DASATINIB contains the active ingredient dasatinib.** Dasatinib is a tyrosine kinase inhibitor and 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 kills the leukaemia cells in the bone marrow and allows normal red cell, white cell, and platelet production to resume.

**TE-DASATINIB 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 TE-DASATINIB be used in adults with:

- newly diagnosed Ph+ CML in the chronic phase 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 TE-DASATINIB 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.

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

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

### **Warnings**

#### **Do not use TE-DASATINIB 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.

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

- have any other medical conditions or problems with your immune system, heart, or liver, are lactose intolerant or have ever had a hepatitis B infection.
- Take any medicines for any other condition.
- Have an allergy to any other substances such as foods, preservatives, or dyes.

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 use TE-DASATINIB if you are pregnant or intend to become pregnant.**

TE-DASATINIB can cause harm to the unborn baby if it is given to a pregnant woman.

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

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

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

Tell your doctor or pharmacist if you or your child 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 interfere with TE-DASATINIB and affect how it works.**

- Nizoral<sup>®</sup> (ketoconazole), Sporanox<sup>®</sup> (itraconazole), Norvir<sup>®</sup> (ritonavir), Reyataz<sup>®</sup> (atazanavir), E-Mycin<sup>®</sup> (erythromycin), Klacid<sup>®</sup> (clarithromycin) and grapefruit juice may all increase the level of TE-DASATINIB in your bloodstream.
- Maxidex<sup>®</sup> (dexamethasone), Dilantin<sup>®</sup> (phenytoin), Tegretol<sup>®</sup> (carbamazepine), Rifadin<sup>®</sup> (rifampicin), and Phenobarbitone tablets may all decrease the levels of TE-DASATINIB in your bloodstream.
- TE-DASATINIB may alter the blood levels of Sandimmun<sup>®</sup> (cyclosporin).
- Blood thinning medicines such as Coumadin<sup>®</sup> (warfarin sodium), aspirin or non-steroidal anti-inflammatory drugs (NSAIDs) taken with TE-DASATINIB may increase the risk of unwanted bleeding.
- Oral diabetes medicines from the glitazone family of drugs may interact with TE-DASATINIB
- You or your child should avoid taking Tagamet<sup>®</sup> (cimetidine), Pepcidine<sup>®</sup> (famotidine), Zantac<sup>®</sup> (ranitidine) or Probitor<sup>®</sup> (omeprazole) while taking TE-DASATINIB as they all reduce stomach acid, which is necessary for the absorption of TE-DASATINIB.

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

be taken up to 2 hours before or 2 hours after TE-DASATINIB.

Some medicines may be affected by TE-DASATINIB 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 TE-DASATINIB.

### **Know the medicines you take.**

Keep a list of you or your child's medicines with you 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 TE-DASATINIB.**

## **4. How do I use TE-DASATINIB?**

### **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 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 TE-DASATINIB.
- Follow the instructions provided and use TE-DASATINIB until your doctor tells you to stop.

## **When to take TE-DASATINIB**

- TE-DASATINIB should be taken at the same time each day, with or without a meal, as instructed by your doctor.

## **How to take TE-DASATINIB**

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

## **How long to take TE-DASATINIB**

- You or your child should not stop taking TE-DASATINIB 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 TE-

DASATINIB, upward or downward, or may temporarily discontinue your medicine.

## **If you forget to use TE-DASATINIB**

TE-DASATINIB 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.

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

**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 think that you have used too much TE-DASATINIB, 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 TE-DASATINIB?**

### **Things you should do**

**Tell your doctor if you are a sexually active man. Men who take TE-DASATINIB are advised to use a condom to avoid pregnancy in their partner.**

**You must tell your doctor immediately if you become pregnant while taking TE-DASATINIB or your partner has been taking TE-DASATINIB.**

**Tell all of the doctors, dentists and pharmacists who are treating you that you or your child are taking TE-DASATINIB.**

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

- become pregnant while taking TE-DASATINIB or your partner has been taking TE-DASATINIB
- or your child experience bleeding or easy bruising, no matter how mild
- develop a fever while taking TE-DASATINIB
- experience shortness of breath and fatigue while taking TE-DASATINIB

**If you or your child are about to be started on any new medicine, tell your doctor and pharmacist that you are taking TE-DASATINIB.**

**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 TE-DASATINIB is working.

## **Things you should not do**

- Do not give TE-DASATINIB to anyone else, even if they have the same condition as you.
- Do not use TE-DASATINIB to treat any other complaints unless your doctor tells you to.
- Do not stop taking TE-DASATINIB, or lower the dosage, without checking with your doctor.
- Do not stop taking TE-DASATINIB because you 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 TE-DASATINIB affects you.**

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

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol is not expected to interact with TE-DASATINIB. If you drink alcohol, talk to your doctor about the possible effects of taking alcohol with this medicine.

## Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in the original pack until it is time to take them. If you take your tablets out of the pack, they may not keep well.

Store TE-DASATINIB in a cool dry place below 25°C, 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 windowsills.

**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.

## Less serious side effects

Less serious side effects	What to do
<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></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>



<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <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>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● changes in the way your heart beats, for example - if you notice it beating faster</li> <li>● bleeding - for example from: gastrointestinal</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
tract; eye; nose; gums; serious bruising or excessive menstrual bleeding <ul style="list-style-type: none"> <li>● infections - urinary tract; eye infection; difficulty breathing; coughing</li> <li>● fever</li> <li>● painful rash with blisters</li> <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> </ul>	<b>notice any of these serious side effects.</b>

**The use of TE-DASATINIB 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.

**Tell your doctor or pharmacist if you notice anything else that may be making you or your child 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 or your child 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 TE-DASATINIB contains**

<b>Active ingredient</b>	Dasatinib
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• lactose monohydrate</li> <li>• microcrystalline cellulose</li> <li>• hypromellose</li> <li>• croscarmellose sodium</li> <li>• magnesium stearate</li> <li>• Opadry White YS-1-7027</li> </ul>

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

## **What TE-DASATINIB looks like**

### **TE-DASATINIB 20 mg tablet**

White to off-white, round film-coated tablets with bevelled edges and debossed "20" on one side of the tablet

### **TE-DASATINIB 50 mg tablet**

White to off-white, oval film-coated tablets with bevelled edges and debossed "50" on one side of the tablet

### **TE-DASATINIB 70 mg tablet**

White to off-white, round film-coated tablets with bevelled edges and debossed "70" on one side of the tablet

### **TE-DASATINIB 100 mg tablet**

White to off-white, oval film-coated tablets with bevelled edges and debossed "100" on one side of the tablet

### **Australian Registration Numbers**

**TE-DASATINIB 20 mg tablet** – 60 tablets per bottle  
AUST R 332649

**TE-DASATINIB 50 mg tablet** – 60 tablets per bottle  
AUST R 332656

**TE-DASATINIB 70 mg tablet** – 60 tablets per bottle  
AUST R 332645

**TE-DASATINIB 100 mg tablet** – 30 tablets per bottle  
AUST R 332642

### **Who distributes TE-DASATINIB?**

TE-DASATINIB is supplied in Australia by:

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

TE-DASATINIB is supplied in New Zealand by:

Teva Pharma (New Zealand) Limited

Auckland, New Zealand

This leaflet was prepared in January 2024.