

DASATINIB-TEVA®

Information for patients prescribed DASATINIB-TEVA® tablets for the treatment of newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukaemia (CML) in the chronic phase; chronic, accelerated or myeloid or lymphoid blast phase chronic myeloid leukaemia with resistance or intolerance to prior therapy including imatinib; newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy; Philadelphia chromosome positive acute lymphoblastic leukaemia with resistance or intolerance to prior therapy in adults aged 18 years or over. Treatment of paediatric patients with: Ph+ CML in the chronic phase and newly diagnosed Ph+ ALL in combination with chemotherapy.¹

When filling a prescription for dasatinib, your pharmacist may dispense the generic brand **Dasatinib-Teva**® instead of the existing brand, **Sprycel**® (Dasatinib). This fact sheet answers some common questions about generic brands and **Dasatinib-Teva**®. If you have any concerns about your treatment or condition, you should discuss these with your doctor or pharmacist.

Are generic and existing brand medicines the same?¹⁻³

Dasatinib-Teva® is a generic brand. It is an additional brand to the existing or original brand, **Sprycel**®. It contains the same active ingredient, dasatinib (the chemical that makes the medicine work), and it works in the same way as **Sprycel**®.

Why has your pharmacist dispensed generic **Dasatinib-Teva**® instead of **Sprycel**®?²

The company that originally developed dasatinib has had the sole rights to manufacture and distribute dasatinib under the brand name **Sprycel**®, under patent protection. That patent has now expired. This means that other pharmaceutical companies now can supply dasatinib under different brand names. Pharmacies may choose to dispense a generic brand, such as **Dasatinib-Teva**®, as their preferred brand when a filling a prescription.

Will generic **Dasatinib-Teva**® tablets work in the same way as **Sprycel**® tablets?¹⁻³

The Australian Government's Therapeutic Goods Administration (TGA) ensures all generic brands meet the same quality standards as the existing brand. **Dasatinib-Teva**® tablets work in the same way as **Sprycel**® tablets because they contain the same active ingredient in the same dose and strength.

How do we know that generic brands are as safe as original brands?²

Generic brands meet the same standards of quality, safety and effectiveness as existing brands. As with all medicines, the TGA continually monitors safety once a generic brand is on the market. If you suspect you have experienced a problem with any medicine, including a generic brand, please report it to the TGA at www.tga.gov.au/reporting-problems

Dasatinib-Teva®		Sprycel®	
20 mg tablet		50 mg tablet	
70 mg tablet		100 mg tablet	
		20 mg tablet	
		50 mg tablet	
		70 mg tablet	
		100 mg tablet	

What are the benefits of generic brands?²

Generic brands may be more affordable for the Government and the Pharmaceutical Benefits Scheme to purchase, which helps make the health system more cost effective. You can ask your doctor to prescribe a generic brand, or ask your pharmacist if they are able to supply you with a more affordable brand of the same medicine.

How to take **Dasatinib-Teva**® tablets⁴

Follow all directions given to you by your doctor or pharmacist carefully. The entire dose prescribed by your doctor should be taken at one time either in the morning or evening. Other things to remember are:

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

Note: If you are switching from **Sprycel**® to **Dasatinib-Teva**® tablets, be sure to stop your **Sprycel**® tablets before starting **Dasatinib-Teva**® at the next scheduled dose. Continue to take **Dasatinib-Teva**® tablets in the same way as **Sprycel**®. Do not take both **Dasatinib-Teva**® and **Sprycel**® tablets.

Should you take extra precautions when switching to **Dasatinib-Teva**® tablets?

The usual precautions you take when taking **Sprycel**® tablets apply. Take tablets at the same dose, around the same time each day.

If you forget to take your **Dasatinib-Teva**® tablets⁴

Dasatinib-Teva® tablets should be taken regularly, and at the same time each day. If you miss your usual dose 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. If you think that you have used too much **Dasatinib-Teva**®, 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 you have no signs of discomfort or poisoning.

What are the possible side effects of **Dasatinib-Teva**® tablets?⁴

All medicines can have side effects. If you do experience any side effects, most of them should be minor and temporary. However, some serious side effects may need medical attention. Please refer to the Consumer Medicine Information for information on the most common side effects.

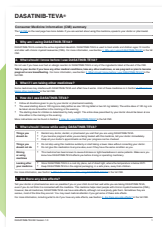
Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.



For further information about **Dasatinib-Teva**®, please ask your doctor or pharmacist for a copy of the Consumer Medicine Information.

Where to get further information

Your doctor is the best person to answer any questions you may have about your condition and treatment with **Dasatinib-Teva**[®]. Other sources of information and support are:



Consumer Medicine Information (CMI)

Read about **Dasatinib-Teva**[®], including how it works, how to take it and common side effects. Your doctor or pharmacist can provide you with a copy of the CMI or it can be accessed at www.tga.gov.au/consumer-medicines-information-cmi



Leukaemia Foundation

There are many organisations that provide support and assistance to people living with cancer including the Leukaemia Foundation www.leukaemia.org.au and Cancer Council www.cancercouncil.com.au



Therapeutic Goods Administration

The Australian Therapeutic Goods Administration (TGA) provides a fact sheet titled Generic Prescription Medicines which can be accessed at www.tga.gov.au/community-qa/generic-prescription-medicines-fact-sheet

ALL: Acute lymphoblastic leukaemia, CML: chronic myeloid leukaemia, PH+: Philadelphia chromosome positive.

References:

1. Dasatinib-Teva[®] Approved Product Information, March 2021.
2. Therapeutic Goods Administration. Generic prescriptions medicines: Fact sheet <https://www.tga.gov.au/community-qa/generic-prescription-medicines-fact-sheet> Accessed September 2021.
3. Sprycel[®] Approved Product Information, June 2020.
4. Dasatinib-Teva[®] Consumer Medicine Information, March 2021.
5. Sprycel[®] Consumer Medicine Information, June 2020.

Sprycel[®] is a registered trademark of Bristol-Myers Squibb Company. Dasatinib-Teva[®] is a registered trademark of TEVA Pharmaceutical Industries Ltd. TEVA Pharma Australia Pty Ltd, ABN 41 169 715 664. Level 1, 37 Epping Road, Macquarie Park, Sydney NSW 2113.

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