

Consumer Medicine Information

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

Where to find information in this leaflet:

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

1. Why am I using DASATINIB-TEVA?

DASATINIB-TEVA 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.

DASATINIB-TEVA 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 DASATINIB-TEVA 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 DASATINIB-TEVA 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 DASATINIB-TEVA was prescribed for you or your child.

2. What should I know before I use DASATINIB-TEVA?

Warnings

Do not use DASATINIB-TEVA 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 DASATINIB-TEVA if you are pregnant or intend to become pregnant. DASATINIB-TEVA can cause harm to the unborn baby if it is given to a pregnant woman.

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

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