

PATIENT INFORMATION

Dasatinib (da-SA-ti-nib) Tablets

What are dasatinib tablets?

Dasatinib tablets are a prescription medicine used to treat:

- adults with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- adults with Ph+ CML who no longer benefit from, or did not tolerate, other treatment, including imatinib.
- adults with Ph+ acute lymphoblastic leukemia (Ph+ ALL) who no longer benefit from, or did not tolerate, other treatment.
- children 1 year of age and older with Ph+ CML in chronic phase.
- children 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.

It is not known if Dasatinib is safe and effective in children under 1 year of age.

Before taking dasatinib tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have problems with your immune system
- have heart problems, including a condition called congenital long QT syndrome
- have low potassium or low magnesium levels in your blood
- have liver problems
- are lactose (milk sugar) intolerant
- are pregnant or plan to become pregnant. Dasatinib can harm your unborn baby.

Females who can become pregnant:

- You should not become pregnant during treatment with dasatinib tablets.
- You should use effective birth control (contraception) during treatment and for 30 days after your last dose of dasatinib tablets.
- Talk to your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with dasatinib tablets.

Males with female partners who can become pregnant:

- You should use effective birth control (contraception) during treatment and for 30 days after your last dose of dasatinib tablets.
- Your female partner should call her healthcare provider if she becomes pregnant or thinks she is pregnant during your treatment with dasatinib tablets.
- are breastfeeding or plan to breastfeed. It is not known if dasatinib passes into your breast milk. You should not breastfeed during treatment and for 2 weeks after your last dose of dasatinib tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, antacids, and herbal supplements. **If you take an antacid medicine, take it 2 hours before or 2 hours after your dose of dasatinib tablets.**

How should I take dasatinib tablets?

- Take dasatinib tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose of dasatinib tablets or temporarily stop treatment

with dasatinib tablets. **Do not change your dose or stop taking dasatinib tablets without first talking to your healthcare provider.**

- Take dasatinib tablet 1 time a day.
- Take dasatinib tablets with or without food, either in the morning or in the evening.
- Swallow dasatinib tablets whole. Do not crush, cut or chew the tablets.
 - If your child cannot swallow tablets whole, talk with your healthcare provider.
- You should not drink grapefruit juice during treatment with dasatinib tablets.
- If you miss a dose of dasatinib tablets, take your next scheduled dose at your regular time. Do not take two doses at the same time.
- If you take too much dasatinib tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of dasatinib tablets?

Dasatinib tablets may cause serious side effects, including:

- **Low blood cell counts.** Low blood cell counts are common with dasatinib tablets and can be severe, including low red blood cell counts (anemia), low white blood cell counts (neutropenia), and low platelet counts (thrombocytopenia). Your healthcare provider will do blood tests to check your blood cell counts regularly during your treatment with dasatinib tablets. Call your healthcare provider right away if you have a fever or any signs of an infection during treatment with dasatinib tablets.
- **Bleeding problems.** Bleeding problems are common with dasatinib tablets. Sometimes these bleeding problems can be serious and lead to death. Call your healthcare provider right away if you have:
 - unusual bleeding or bruising of your skin
 - bright red or dark tar-like stools
 - decreased alertness, headache, or change in speech
- **Your body may hold too much fluid (fluid retention).** Fluid retention is common with dasatinib tablets and can sometimes be severe. In severe cases, fluid may build up in the lining of your lungs, the sac around your heart, or your stomach cavity. Call your healthcare provider right away if you get any of these symptoms during treatment with dasatinib tablets:
 - swelling all over your body
 - weight gain
 - shortness of breath, especially if this happens with low levels of physical activity or at rest
 - dry cough
 - chest pain when taking a deep breath
- **Heart and blood vessel (cardiovascular) problems.** Dasatinib tablets may cause heart problems, including an abnormal heart rate, a heart attack, or small strokes that last only a few minutes or a few hours, called transient ischemic attacks (TIAs). TIAs are often a warning sign that you are at risk for a more serious stroke. Your healthcare provider will monitor the potassium and magnesium levels in your blood and your heart function.

Get medical help right away if you develop any of the following symptoms during treatment with dasatinib tablets:

- chest pain
- shortness of breath
- feeling like your heart is beating too fast or you feel abnormal heart beats
- vision changes that may last for a short time
- slurred speech
- **Pulmonary Arterial Hypertension (PAH).** Dasatinib tablets may cause high blood pressure in the vessels of your lungs. PAH may happen at any time during your treatment with dasatinib tablets. Your healthcare provider should check your heart and lungs before and during treatment with

dasatinib tablets. Call your healthcare provider right away if you have shortness of breath, tiredness, or swelling all over your body (fluid retention).

- **Severe skin reactions.** Dasatinib tablets may cause skin reactions that can sometimes be severe. Get medical help right away if you get a skin reaction with fever, sore mouth or throat, or blistering or peeling of your skin or in the mouth.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure and the need for dialysis treatment, and an abnormal heartbeat. Your healthcare provider may do blood tests to check you for TLS. Call your healthcare provider or get emergency medical help right away if you develop any of these symptoms during treatment with dasatinib tablets:
 - nausea
 - vomiting
 - weakness
 - swelling
 - shortness of breath
 - muscle cramps
 - seizures

- **Slowing of growth and development in children.** Effects on bone growth and development in children have happened with dasatinib tablets and can sometimes be severe. Your healthcare provider will monitor your child's bone growth and development during treatment with dasatinib tablets. Get medical help right away if your child develops bone pain.
- **Liver problems.** Dasatinib tablets can cause liver problems. People who have had liver problems in the past may be at risk for getting liver problems with dasatinib tablets. Your healthcare provider will monitor your liver function as needed during the treatment with dasatinib tablets. Call your healthcare provider or get medical help right away if you develop any symptoms of liver problems, including:
 - stomach-area (abdominal) pain
 - bleeding
 - yellowing of your skin or white part of your eyes
 - bruising
 - loss of appetite
 - dark "tea-colored" urine

The most common side effects of dasatinib tablets in adults and children receiving dasatinib tablets alone include:

- diarrhea
- headache
- skin rash
- shortness of breath
- tiredness
- nausea
- muscle pain

The most common side effects of dasatinib tablets in children receiving dasatinib tablets with chemotherapy include:

- swelling, pain and redness of the lining of your mouth, throat, stomach and bowel (mucositis)
- low white blood cell counts with fever
- fever
- diarrhea
- nausea
- vomiting
- muscle pain
- tiredness
- constipation
- abnormal heart rate
- high blood pressure (hypertension)
- swelling
- infections
- low blood pressure

- stomach (abdominal) pain
- cough
- headache
- rash
- decreased appetite
- allergic reactions
- shortness of breath
- nose bleed
- numbness or tingling of your hands and feet
- feeling confused or disoriented

Dasatinib tablets may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of dasatinib.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store dasatinib tablets?

- Store dasatinib tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Ask your healthcare provider or pharmacist about the right way to throw away expired or unused dasatinib tablets.
- Wear latex or nitrile gloves when handling tablets that have accidentally been crushed or broken.
- Females who are pregnant should not handle crushed or broken dasatinib tablets.

Keep dasatinib tablets and all medicines out of the reach of children.

General information about the safe and effective use of dasatinib tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use dasatinib tablets for a condition for which it is not prescribed. Do not give dasatinib tablets to other people even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about dasatinib that is written for health professionals.

For more information, go to *www.apotex.com* or call Apotex Corp at 1-800-706-5575

What are the ingredients in dasatinib tablets?

Active ingredient: dasatinib

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose. The tablet coating consists of hydroxypropyl cellulose, hypromellose, titanium dioxide and triethyl citrate.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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**APOTEX INC.
DASATINIB TABLETS
20 mg, 50 mg, 70 mg and 100 mg**

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Revised: February 2024
Revision 14