



LAB-0443-10.0

PATIENT INFORMATION
BOSULIF® (BAH-su-lif)
(bosutinib)
tablets

What is BOSULIF?

BOSULIF is a prescription medicine used to treat adults who have a certain type of leukemia called Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) who are newly-diagnosed or who no longer benefit from or did not tolerate other treatment.

It is not known if BOSULIF is safe and effective in children less than 18 years of age.

Do not take BOSULIF if you are allergic to bosutinib or any of the ingredients in BOSULIF. See the end of this leaflet for a complete list of ingredients of BOSULIF.

Before taking BOSULIF, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have heart problems
- have kidney problems
- are pregnant or plan to become pregnant. BOSULIF can harm your unborn baby. Females who are able to become pregnant should have a pregnancy test before starting treatment with BOSULIF. Tell your doctor right away if you become pregnant during treatment with BOSULIF.
 - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with BOSULIF and for at least 1 month after the last dose. Talk to your doctor about birth control methods that may be right for you.
- are breastfeeding or plan to breastfeed. It is not known if BOSULIF passes into your breast milk or if it can harm your baby. Do not breastfeed during treatment with BOSULIF and for at least 1 month after the last dose.

Tell your doctor about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. When taken together, BOSULIF and certain other medicines can affect each other.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take BOSULIF?

- Take BOSULIF exactly as prescribed by your doctor.
- Do not change your dose or stop taking BOSULIF without first talking with your doctor.
- Take BOSULIF with food.
- Swallow BOSULIF tablets whole. Do not crush, break, or cut BOSULIF tablets. Do not touch or handle crushed or broken BOSULIF tablets.
- If you take an antacid or H₂ blocker medicine, take it at least 2 hours before or 2 hours after BOSULIF. If you take a Proton Pump Inhibitor (PPI) medicine, talk to your doctor or pharmacist.
- You should avoid grapefruit, grapefruit juice, and supplements that contain grapefruit extract during treatment with BOSULIF. Grapefruit products increase the amount of BOSULIF in your body.
- If you miss a dose of BOSULIF, take it as soon as you remember. If you miss a dose by more than 12 hours, skip that dose and take your next dose at your regular time. Do not take 2 doses at the same time.
- If you take too much BOSULIF, call your doctor or go to the nearest hospital emergency room right away.

PATIENT INFORMATION**BOSULIF (BAH-su-lif)****(bosutinib)****tablets****What are the possible side effects of BOSULIF?****BOSULIF may cause serious side effects, including:**

- **Stomach problems.** BOSULIF may cause stomach (abdomen) pain, nausea, diarrhea, or vomiting. Tell your doctor about any stomach problems.
- **Low blood cell counts.** BOSULIF may cause low platelet counts (thrombocytopenia), low red blood cell counts (anemia) and low white blood cell counts (neutropenia). Your doctor should do blood tests to check your blood cell counts regularly during your treatment with BOSULIF. Call your doctor right away if you have unexpected bleeding or bruising, blood in your urine or stools, fever, or any signs of an infection.
- **Liver problems.** BOSULIF may cause liver problems. Your doctor should do blood tests to check your liver function regularly during your treatment with BOSULIF. Call your doctor right away if your skin or the white part of your eyes turns yellow (jaundice) or you have dark "tea color" urine.
- **Your body may hold too much fluid (fluid retention).** Fluid may build up in the lining of your lungs, the sac around your heart, or your stomach cavity. Call your doctor right away if you get any of the following symptoms during your treatment with BOSULIF:
 - shortness of breath and cough
 - chest pain
 - swelling in your hands, ankles, or feet
 - swelling all over your body
 - weight gain
- **Kidney problems.** BOSULIF may cause kidney problems. Your doctor should do tests to check your kidney function when you start treatment with BOSULIF and during your treatment. Call your doctor right away if you get any of the following symptoms during your treatment with BOSULIF:
 - you urinate more often than normal
 - you urinate less often than normal
 - you make a much larger amount of urine than normal
 - you make a much smaller amount of urine than normal

The most common side effects of BOSULIF in people with newly-diagnosed CML include:

- diarrhea
- nausea
- low platelet counts
- rash
- changes in liver function test
- stomach (abdomen) pain

The most common side effects of BOSULIF in people with CML who no longer benefit from or did not tolerate other treatment include:

- diarrhea
- nausea
- stomach (abdomen) pain
- rash
- low platelet counts
- vomiting
- low red blood cell counts
- tiredness
- fever
- cough
- headache
- change in liver function test
- swelling

Tell your doctor right away if you get respiratory tract infections, loss of appetite, headache, dizziness, back pain, joint pain, or itching while taking BOSULIF. These may be symptoms of a severe allergic reaction.

Your doctor may change your dose, temporarily stop, or permanently stop treatment with BOSULIF if you have certain side effects.

BOSULIF may cause fertility problems in females and males. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

Tell your doctor 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 BOSULIF. For more information, ask your doctor or pharmacist.

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