

Addressing side effects during BOSULIF[®] (bosutinib) treatment



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



EXPERIENCING SIDE EFFECTS OF TREATMENT

BOSULIF may cause a range of side effects. Serious side effects include stomach problems, low blood cell counts, liver problems, fluid retention, and kidney problems.

The most common side effects of BOSULIF include: diarrhea, nausea, low blood cell counts, rash, vomiting, stomach pain, respiratory tract infection, fever, abnormal liver function, tiredness or weakness, cough, headache.



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.

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.



COMMUNICATING WITH YOUR DOCTOR AND HEALTHCARE TEAM

You and your doctor may be able to help manage some of the side effects that you experience while taking BOSULIF.

Be sure to pay attention to all your side effects. They may be signs that let you and your doctor know what is happening in your body. Work with your healthcare team to determine when you should call with questions or concerns.



DOSE ADJUSTMENTS

A dose adjustment is when your doctor changes the amount of BOSULIF you're taking, in order to best tailor your therapy to your individual needs.

Your doctor may either change your dose of BOSULIF or tell you to stop taking BOSULIF, depending on how you are doing on treatment, as this may help manage side effects and response to treatment. Working with your healthcare team to customize therapy is an important way to help you start and stay on treatment.

DIARRHEA

One of the most common side effects associated with BOSULIF was diarrhea. 82% of patients in the clinical trial experienced episodes of diarrhea while taking BOSULIF, and 1% of those patients discontinued treatment because of diarrhea.

Diarrhea experienced by patients in the clinical trial



*The median is the “middle value” in a list of numbers. It is a kind of measurement. For example, if the median number of episodes of diarrhea is 3, half of the patients in the study experienced 3 or more episodes of diarrhea, and half experienced 3 or less episodes of diarrhea.

When you start taking BOSULIF, it may be helpful to ask your doctor how to prepare for possible episodes of diarrhea.

If you have diarrhea, call your doctor. Your doctor may recommend you take medicine to treat diarrhea. Always talk to your doctor before taking any over-the-counter medicines. Your doctor may choose to have you stop taking BOSULIF for a period of time or change your dose to help manage diarrhea.

SERIOUS SIDE EFFECTS

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 or less often than normal
 - you make a much larger or smaller amount of urine than normal



For more information on possible side effects, including diarrhea, please visit www.bosulif.com.

HOW TO HELP MANAGE COMMON SIDE EFFECTS

Side effect	Management tips to discuss with your doctor or nurse
Diarrhea	<ul style="list-style-type: none">✓ Eat mild foods✓ Drink water often✗ Avoid spicy foods, fatty foods, caffeine, and raw fruit
Nausea or vomiting	<ul style="list-style-type: none">✓ Eat smaller, more frequent meals✓ Drink fluids in small amounts✗ Avoid foods that are sweet, fried, or fatty
Rash	<ul style="list-style-type: none">✓ Wear loose clothing that does not rub against your skin too much✗ Avoid hot water when washing hands, bathing, or showering✗ Avoid soaking in long baths
Stomach pain	<ul style="list-style-type: none">✓ Sleep in a more upright position, propped up on a pillow✓ Reduce your stress with meditation, yoga, or music✗ Avoid large meals, coffee, and alcohol
Respiratory tract infection	<ul style="list-style-type: none">✓ Take acetaminophen to reduce aches and pain✓ Drink plenty of fluids, including warm drinks with honey and lemon✗ Do not smoke
Fever	<ul style="list-style-type: none">✓ Take antibiotics (if your doctor thinks the fever is caused by a bacterial infection)✓ Take acetaminophen
Tiredness or weakness	<ul style="list-style-type: none">✓ Take short naps or breaks✓ Eat well and drink plenty of fluids✓ Take short walks or do light exercise if you feel up to it✓ Do things that are relaxing, such as listening to music or reading
Cough	<ul style="list-style-type: none">✓ Drink warm fluids with honey and lemon✓ Suck on sore throat lozenges✓ Use a humidifier or take a steamy shower
Headache	<ul style="list-style-type: none">✓ Close your eyes and rest✓ Massage your neck and temples✓ Take acetaminophen✗ Do not drink alcohol



Remember to tell your doctor if you have any side effect that bothers you or that does not go away.

Your doctor may also be able to recommend some over-the-counter medicines that could help you with some of the above side effects, or your doctor may adjust your dose of BOSULIF.

Not all side effects can be managed. These are not all of the possible side effects of BOSULIF. For more information, ask your doctor or pharmacist.

Indication

BOSULIF is a prescription medicine used to treat adults who have a type of leukemia called Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) 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.

Important Safety Information for patients

Do not take BOSULIF if you are allergic to bosutinib or any of the ingredients in BOSULIF.

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 - you urinate more or less often than normal
 - you make a much larger or smaller amount of urine than normal

- **The most common side effects of BOSULIF include:** diarrhea, nausea, low blood cell counts, rash, vomiting, stomach pain, respiratory tract infection, fever, abnormal liver function, tiredness or weakness, cough, and headache

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.

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Tell your doctor about the medicines you take, including prescription medicines, non-prescription medicines, vitamins, and herbal supplements. BOSULIF and certain other medicines can affect each other.

Before you take BOSULIF, tell your doctor if you:

- have liver problems
- have heart problems
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. BOSULIF can harm your unborn baby. You should not become pregnant while taking BOSULIF. Tell your doctor right away if you become pregnant while taking BOSULIF
- are a woman who may become pregnant. Use effective contraception (birth control) during and for at least 30 days after completing treatment with BOSULIF. Talk to your doctor about forms of birth control
- are breastfeeding or plan to breastfeed. It is not known if BOSULIF passes into your breast milk or if it can harm your baby. You and your doctor should decide if you will take BOSULIF or breastfeed. You should not do both

You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit <http://www.fda.gov/MedWatch> or call 1-800-FDA-1088.

Visit www.bosulif.com for more information.

Please see [full Prescribing Information](#) and [Patient Product Information](#) available on [BOSULIF.com](#).



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