

Bosutinib (Bosulif)

About This Medicine

BOSUTINIB (boe SUE ti nib) treats leukemia. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- · Pain in your abdomen
- Tiredness
- Fever
- Decreased appetite (decreased hunger)
- Electrolyte changes
- Blood sugar levels may change
- Increased uric acid level in your blood
- Increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Changes in your liver and/or pancreas function
- Changes in your kidney function
- Headache
- · Respiratory tract infection
- Rash

Note: Each of the side effects above was reported in 20% or greater of people treated with bosutinib. All possible side effects are not included. Your side effects may be different depending on your cancer



diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- · Severe nausea, vomiting, diarrhea, and pain in your abdomen
- Severe bone marrow suppression
- Severe changes in your kidney function which can cause kidney failure
- Severe changes in your liver function which can cause liver failure
- Changes in your heart function such as heart attack and congestive heart failure your heart is not pumping blood as well as it should be, and fluid can build up in your body.
- Swelling of the hands, feet, or any other part of the body. Fluid can also accumulate around your heart or around your lungs.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

How to Take Your Medicine

- Tablets: Swallow tablets whole with food. Do not cut, break, or crush it. Do not touch a broken or crushed tablet.
- Capsules: Swallow capsules whole with food. If you cannot swallow capsules whole, the capsules can be opened, and the contents can be mixed with applesauce or yogurt. Gloves must be worn to open capsules. Do not mix with other foods. Swallow the mixture right away, without chewing. Do not store the mixture for later use. Take the mixture with a full meal. Please follow the instructions that are given with this medicine for more details on how much applesauce or yogurt you should use based on the dosage of bosutinib you are prescribed.
- If you take an antacid or H2 blocker, take bosutinib at least 2 hours before or 2 hours after you take the antacid or H2 blocker. If you take a proton pump inhibitor medicine, talk with your care team.
- Missed dose: If you miss a dose, take it as soon as you think about it unless you missed your dose
 by more than 12 hours, then skip the missed dose and take your next dose at the regular time. Do
 not take 2 doses at the same time or extra doses.
- **Overdosage**: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage: Tablets:** Store tablets in the original container at room temperature. Do not throw away or eat the desiccant in the bottle. Keep out of the reach of children and pets.
- Capsules: Store capsules in the original container at room temperature. Keep out of the reach of children and pets.



• **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a
 fever.
- To decrease the risk of bleeding, use a soft toothbrush. Check with your before using dental floss.
- Be very careful when using knives or tools.
- · Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicine that can lessen or stop your diarrhea and/or constipation.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose food and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of bosutinib
 in your body which could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this



medicine as there are known medicine interactions with bosutinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplement to make sure that there are no interactions.

- Avoid the use of St. John's Wort while taking bosutinib as this may lower the levels of the medicine in your body, which can make it less effective.
- Medicines that treat heartburn and stomach upset may lower the effect of your cancer treatment if taken with bosutinib. Call your care team to find out what medicine you can take with bosutinib to help with heartburn or stomach upset.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back, or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. If any of these symptoms last 2 minutes, call 911.
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- · Wheezing and/or trouble breathing
- Cough that is bothersome or coughing up yellow, green, or bloody mucus
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Pain in your abdomen that does not go away
- Unexplained muscle pain, tenderness, or weakness
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Blood in your stool
- Swelling of the hands, feet, or any other part of the body
- · Lasting loss of appetite or rapid weight loss of five pounds in a week
- Weight gain of 5 pounds in one week (fluid retention)
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- · Decreased or very dark urine
- New rash and/or itching



Rash that is not relieved by prescribed medicines

Reproduction Warnings

- **Pregnancy warning**: This medicine may/can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 2 weeks after the last dose. Tell your care team right away if you think you might be pregnant.
- Breastfeeding warning: Do not breastfeed while taking this medicine and for 2 weeks after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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