



STARTING YOUR JOURNEY

with BOSULIF[®] (bosutinib)

ADULT TREATMENT GUIDE

INDICATIONS

BOSULIF is a prescription medicine used to treat:

- adults who have a certain type of leukemia called chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) who are newly diagnosed or who no longer benefit from or did not tolerate other treatment
- adults with accelerated phase (AP) or blast phase (BP) Ph+ CML who can no longer benefit from or did not tolerate other treatment

Please see a brief summary of **IMPORTANT FACTS** about BOSULIF on pages 4 and 5. [CLICK HERE](#) for full Prescribing Information including instructions for use.

 **Bosulif**[®]
bosutinib
tablets 500 mg | 400 mg | 100 mg
capsules 100 mg | 50 mg

YOUR ADULT TREATMENT GUIDE TO BOSULIF® (BOSUTINIB)

Starting a new treatment can come with many questions. In this brochure, you will find information on many topics that may help you:

- Understand CML
- Manage your treatment and side effects
- Find resources and support

Throughout this brochure, you will notice that some terms **are underlined**; they are defined under “Terms to Know.”

WHAT IS CML?

CML is chronic myelogenous leukemia. It is a type of cancer in your blood and bone marrow.

When you have CML, irregular white blood cells (WBCs) grow uncontrollably in your bone marrow and collect in your blood. These are called leukemia cells. Over time, the leukemia cells crowd out healthy WBCs, red blood cells, and platelets.

WHAT CAUSES CML?

CML can be caused by an abnormal chromosome called the **Philadelphia chromosome (Ph)**. If your CML is caused by this chromosome, it may also be referred to as Ph+ CML. This abnormal chromosome produces an abnormal protein called **BCR-ABL**. BCR-ABL causes the leukemia cells to grow and divide out of control.

HOW IS CML TREATED?

Medicines called **tyrosine kinase inhibitors (TKIs)** can block BCR-ABL function, slowing the growth of abnormal WBCs. For some patients, this allows their WBCs to return to normal levels.

WHY AM I TAKING BOSULIF?

BOSULIF is a treatment for:

- **ADULT PATIENTS WITH NEWLY DIAGNOSED CHRONIC PHASE Ph+ CML**
This means you are being treated for the first time
- **ADULT PATIENTS WITH CHRONIC, ACCELERATED, OR BLAST PHASE Ph+ CML WITH RESISTANCE OR INTOLERANCE TO PRIOR THERAPY**

This means your medicine no longer works to control your CML or you can no longer take your current medicine due to unmanageable side effects

Do not take BOSULIF if you are allergic to bosutinib or any of the ingredients in BOSULIF. It is not known if BOSULIF is safe and effective in children less than 1 year of age with CP Ph+ CML who are newly diagnosed or who no longer benefit from or did not tolerate other treatment or in children with AP Ph+ CML or BP Ph+ CML.

TELL ALL OF YOUR HEALTHCARE PROVIDERS THAT YOU ARE TAKING BOSULIF

TERMS TO KNOW

BCR-ABL: An abnormal protein that causes the bone marrow to produce leukemia cells.

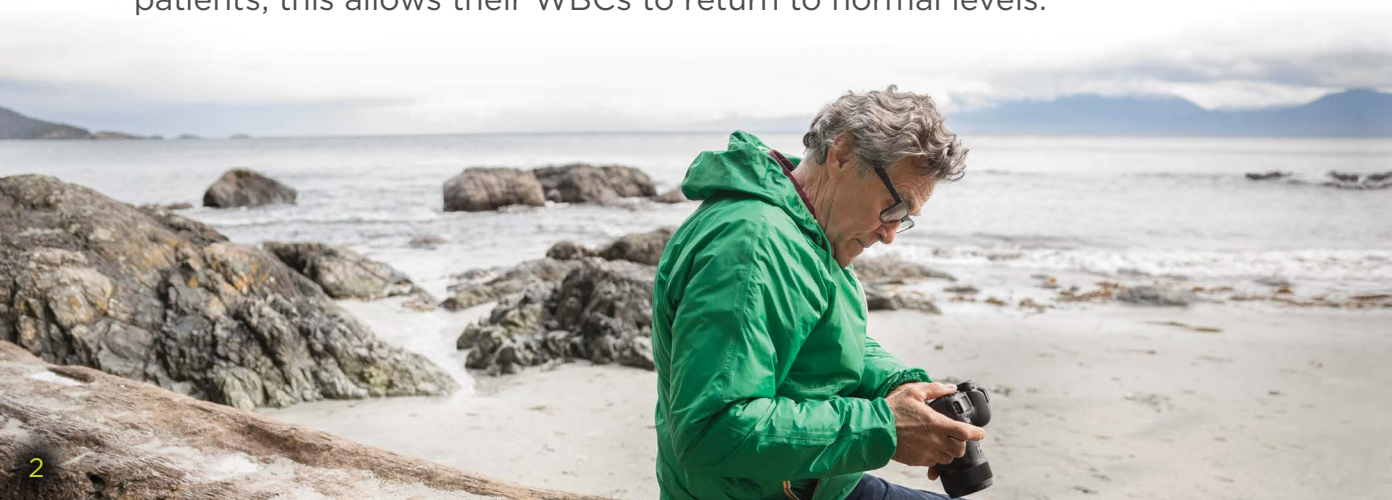
Bone marrow: The soft, sponge-like tissue in the center of most bones. It makes WBCs, red blood cells, and platelets.

Tyrosine kinase inhibitors (TKIs): In CML, a TKI is used to block the activity of BCR-ABL protein (a tyrosine kinase); this slows leukemia cell growth.

Philadelphia chromosome (Ph): An abnormality in your chromosome that results in the production of BCR-ABL protein. This protein causes leukemia cells to grow uncontrollably.

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BOSULIF MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:

- **Stomach problems.** BOSULIF may cause stomach (abdomen) pain, nausea, diarrhea, vomiting, or blood in your stools. Get medical help right away for 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.** 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
- **Heart problems.** BOSULIF may cause heart problems, including heart failure and decreased blood flow to the heart, which can lead to heart attack. Get medical help right away if you get shortness of breath, weight gain, chest pain, or swelling in your hands, ankles, or feet
- **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. Get medical help 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

SIDE EFFECTS (cont'd)

- **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

The most common side effects of BOSULIF in adults with CML include diarrhea, rash, nausea, stomach (abdomen) pain, vomiting, tiredness, liver problems, respiratory tract infections (infections in nose, throat, or lungs), fever, headache, constipation, and changes in certain blood tests. Your doctor may do blood tests during treatment with BOSULIF to check for changes.

Tell your doctor or get medical help right away if you get respiratory tract infections, loss of appetite, headache, dizziness, back pain, joint pain, rash, 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 both female and male patients. 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. You may report side effects to FDA at 1-800-FDA-1088.

DEALING WITH DIARRHEA

Diarrhea

Most patients in the clinical studies of BOSULIF experienced diarrhea. Nine percent of adult patients who were newly diagnosed and 10% of adult patients with CP CML treated before experienced episodes of **severe diarrhea**.

Before starting BOSULIF, ask your healthcare team how to prepare for possible episodes of diarrhea.

If you have diarrhea, call your healthcare team. Your healthcare team may recommend you take medicine to treat diarrhea. Always talk to your doctor before taking any over-the-counter medicines. Your doctor may change your dose, temporarily stop, or permanently stop treatment with BOSULIF to help manage diarrhea.

Experience from the clinical studies			
	What percentage of chronic phase patients experienced diarrhea?	How soon after starting treatment did diarrhea occur? ^a	How long did episodes of diarrhea last? ^c
Newly diagnosed adult patients	75%	Median of 4 days	Median of 3 days
Adult patients who were treated before	85%	Median of 2 days ^b	Median of 2 days ^b

^aMedian length of time starting treatment that diarrhea occurred.

^bIncludes patients with advanced phase disease.

^cMedian length of each diarrhea episode.

TERMS TO KNOW

Median: The median is the midpoint in a range of numbers, where exactly half of the numbers are below and half of the numbers are above that point.

Severe diarrhea: Severe diarrhea is 7 or more stools/bowel movements per day over baseline.

MANAGEMENT TIPS FOR POTENTIAL SIDE EFFECTS

The table below contains information about some common side effects of BOSULIF and tips that may help manage them. It's important to discuss this content with your healthcare team and set up a plan for managing any side effects you may have. Ask your healthcare team if there are over-the-counter or prescription medicines that may help you. Not all side effects are manageable. Your doctor may change your dose or tell you to stop taking BOSULIF.

DIARRHEA	<ul style="list-style-type: none"> ✓ Hydrate: Drink lots of water ✗ Don't irritate: Eat mild foods. Avoid spicy, heavy, or sugary foods, and caffeine
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 ✗ Avoid soaking in long, hot baths
HEARTBURN/INDIGESTION	<ul style="list-style-type: none"> ✓ Sleep in a more upright position, propped up on a pillow ✓ Reduce stress ✗ Avoid large meals, coffee, and alcohol
COUGH	<ul style="list-style-type: none"> ✓ Eat well and drink plenty of fluids ✓ Suck on sore throat lozenges
FEVER	<ul style="list-style-type: none"> ✓ Take medicine to control fever as recommended by your healthcare team
TIREDNESS OR WEAKNESS	<ul style="list-style-type: none"> ✓ 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
HEADACHE	<ul style="list-style-type: none"> ✓ Increase self-care activities like sleep, and meditation ✗ Limit alcohol intake



QUICK TIP: TRACK HOW YOU'RE FEELING ON THE MYTHERAPY® APP

Track how you're feeling so that together you and your healthcare team can set up a plan for managing any side effects you may have.

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HOW SHOULD I TAKE BOSULIF?

BOSULIF® (bosutinib) tablets are available in 400-mg, 500-mg, and 100-mg strengths, while capsules come in 100-mg and 50-mg strengths. Tablets and capsules should be taken once daily with food.



Tablets and capsules are not shown at actual size.

ADULT RECOMMENDED STARTING DOSAGE

ADULTS WHO WERE NEWLY DIAGNOSED	Your doctor may start you on one 400-mg dose per day
ADULTS WITH RESISTANCE OR TOLERANCE TO OTHER TREATMENTS	Your doctor may start you on one 500-mg dose per day

This can vary, though, depending on your individual needs. Your doctor or HCP may adjust your dose or tell you to stop taking BOSULIF if there are issues or concerns about tolerability.

ONLY YOUR DOCTOR CAN TELL YOU IF CHANGING YOUR DOSE IS APPROPRIATE IN MANAGING YOUR THERAPY




What is a dose adjustment?


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 change your dose of BOSULIF depending on how you are doing on treatment, as it may help manage side effects and response to treatment.

IT IS IMPORTANT TO TAKE BOSULIF EXACTLY AS PRESCRIBED

Follow the instructions below and talk with your healthcare team for more information.

WHAT TO DO







-  **BOSULIF is taken by mouth once a day**
-  **BOSULIF should be taken with food**
 - It may help to take BOSULIF with the same meal every day to make it part of your routine
-  **Swallow BOSULIF tablets whole**
-  **Swallow BOSULIF capsules whole**



- 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
- Wait at least 2 hours before or 2 hours after taking BOSULIF to take an antacid or H₂ blocker medicine

If you cannot swallow BOSULIF capsules whole, see the "**Instructions for Use**" for detailed instructions on how to prepare and give a dose of BOSULIF capsules by opening the capsules and mixing the capsule contents with applesauce or yogurt.

WHAT NOT TO DO

-  **DO NOT change your dose or stop taking BOSULIF without first talking to your doctor.**
-  **DO NOT consume grapefruit, grapefruit juice, and supplements that contain grapefruit extract.** Grapefruit products increase the amount of BOSULIF in your body.
-  **DO NOT crush, break, or cut BOSULIF tablets.** Do not touch or handle crushed or broken BOSULIF tablets.
-  **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.
-  **DO NOT take a proton pump inhibitor (PPI) medicine without talking to your healthcare team first.**
-  **DO NOT mix BOSULIF capsules with other foods besides apple sauce or yogurt.** Do not store the mixture for later use. If you do not swallow the entire BOSULIF mixture, do not mix another dose.

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HOW DO MY DOCTOR AND I KNOW IF MY CML IS RESPONDING TO TREATMENT?

Frequent monitoring and blood tests are very important, so ask your doctor about getting tests that gauge the status of your disease and how you are responding to treatment. Monitoring with quantitative polymerase chain reaction (qPCR) every 3 months is recommended for all patients after initiating therapy, including those who meet response milestones at 3, 6, and 12 months.*

In CML, qPCR measures the amount of the *BCR-ABL* cancer gene. qPCR-International Scale (IS) is the amount of *BCR-ABL* cancer gene you have in your blood compared to baseline. After the level of *BCR-ABL* declines to $\leq 1\%$, molecular monitoring is recommended every 3 months for 2 years and every 3 to 6 months thereafter.

Measures of response in CML*	
Complete hematologic response	A return of blood cell counts to normal levels
Complete cytogenetic response (CCyR)	When there are no cells with the Philadelphia chromosome (Ph+) in your bone marrow
Molecular response	A decrease in the amount of the <i>BCR-ABL</i> cancer gene

Below are qPCR-IS molecular response milestones that your healthcare team will try to achieve with treatment:

qPCR milestones*	
	100% of baseline Your <i>BCR-ABL</i> level before treatment
	10% of baseline—1-log reduction
	1% of baseline—2-log reduction
	0.1% of baseline—3-log reduction
	0.0032% of baseline—4.5-log reduction

Two types of responses your doctor may mention are EMR and MMR

- EMR is early molecular response, which means that at 3 and 6 months, the amount of *BCR-ABL* in your blood is $\leq 10\%$ of when you started treatment
- MMR is major molecular response, which means the amount of *BCR-ABL* is $\leq 0.1\%$ of what it was when you started treatment

WHAT ELSE SHOULD BE MONITORED DURING TREATMENT?

Your doctor may order blood tests:

- To monitor your **blood cell counts** regularly during your treatment with BOSULIF® (bosutinib). 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
- To monitor 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

LEARN MORE ABOUT HOW BOSULIF WAS STUDIED IN CLINICAL TRIALS AT [BOSULIF.COM](https://www.bosulif.com)



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REMINDERS TO MAKE THE MOST OF YOUR TREATMENT

Make sure to tell your healthcare team of any changes in:



Your prescription or any new medicines you start taking.



How you are feeling, even if you think it is not related to your CML.



Side effects, including ones that bother you or do not go away.



Your lifestyle, including any new health issues that may arise.

Start a routine



Take your medicine at the same time every day. Consider taking BOSULIF® (bosutinib) in the morning with breakfast or in the evening with dinner.



Quick Tip: Use the MyTherapy® app or another digital planner or calendar to set up daily reminders to take your medicine.



If you are prescribed BOSULIF capsules, store them in the original bottle.



DON'T MISS A DOSE - SIMPLIFY MEDICATION REMINDERS

Scan the QR code to download the MyTherapy® app and set daily reminders

Your healthcare team can help you with side effects

When you start treatment, consider asking your doctor how to prepare for possible episodes of diarrhea, the most common side effect of BOSULIF.

↑ Dose adjustments from your doctor, lifestyle management, and monitoring over time may help you manage side effects.

Pfizer Oncology together™

Financial Assistance



We'll help you find financial assistance options for your prescribed BOSULIF, regardless of your insurance coverage.

We can also help identify resources if you have Medicare, another government insurance plan, or don't have health insurance.

Co-pay assistance: Eligible, commercially insured patients may pay as little as \$0 per month for BOSULIF.* Limits, terms, and conditions apply. There are no income requirements, forms, or faxing to enroll.

*Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico. Patients may receive up to \$9,450 per product in savings annually. **The offer will be accepted only at participating pharmacies. This offer is not health insurance.** No membership fees apply. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For any questions, please call 1-877-744-5675, visit PfizerOncologyTogether.com/terms or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

Co-Pay Card Terms and Conditions

By using this co-pay card, you acknowledge that you currently meet the eligibility criteria and will comply with the Terms and Conditions described below:

- Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico (formerly known as "La Reforma de Salud").
- Patient must have private insurance. Offer is not valid for cash paying patients. The value of this co-pay card is limited to \$9,450 per use or the amount of your co-pay, whichever is less.
- This co-pay card is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plan or other private health or pharmacy benefit programs.
- You must deduct the value of this co-pay card from any reimbursement request submitted to your private insurance plan, either directly by you or on your behalf. (cont'd on next page)



FOR LIVE, PERSONALIZED SUPPORT
Call 1-877-744-5675 (Monday-Friday 8 AM-8 PM ET)

VISIT
PfizerOncologyTogether.com

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Co-Pay Card Terms and Conditions (continued)

- You are responsible for reporting use of the co-pay card to any private insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the co-pay card, as may be required. You should not use the co-pay card if your insurer or health plan prohibits use of manufacturer co-pay cards.
- This co-pay card is not valid where prohibited by law.
- The benefit under the co-pay card program is offered to, and intended for the sole benefit of, eligible patients and may not be transferred to or utilized for the benefit of third parties, including, without limitation, third party payers, pharmacy benefit managers, or the agents of either.
- This co-pay card cannot be combined with any other external savings, free trial or similar offer for the specified prescription (including any program offered by a third party payer or pharmacy benefit manager, or an agent of either, that adjusts patient cost-sharing obligations, through arrangements that may be referred to as “accumulator” or “maximizer” programs).
- Third party payers, pharmacy benefit managers, or the agents of either, are prohibited from assisting patients with enrolling in the co-pay card program.
- **Co-pay card will be accepted only at participating pharmacies.**
- **If your pharmacy does not participate, you may be able to submit a request for a rebate in connection with this offer.**
- **This co-pay card is not health insurance.**
- Offer good only in the U.S. and Puerto Rico.
- Co-pay card is limited to 1 per person during this offering period and is not transferable.
- A co-pay card may not be redeemed more than once per 30 days per patient.
- No other purchase is necessary.
- Data related to your redemption of the co-pay card may be collected, analyzed, and shared with Pfizer for market research and other purposes related to assessing Pfizer’s programs. Data shared with Pfizer will be aggregated and de-identified; it will be combined with data related to other co-pay card redemptions and will not identify you.
- **Pfizer reserves the right to rescind, revoke, or amend this offer without notice.**
- **Offer expires 12/31/2024.**
- **If your pharmacy does not participate, you may be able to submit a request for a rebate in connection with this offer. Mail a copy of the patient’s pharmacy receipt indicating patient name, name of medication purchased, price paid, and date purchased, along with a copy of the patient’s Pfizer Oncology Together Co-Pay Savings Card, to:**

**Pfizer Oncology Together Co-Pay Savings Program
2250 Perimeter Park Drive, Suite 300
Morrisville, NC 27560**

ARE YOU A CAREGIVER FOR A PATIENT WITH CML?

As you support your loved one on their treatment journey, use this treatment guide to help both of you:

- Understanding their disease and treatment
- Create a routine for taking BOSULIF® (bosutinib) that’s easy to follow
- Prepare for and manage potential side effects

How can you make a difference in a loved one’s treatment?

- Give them emotional support
- Remind them of their dosing schedule
- Join them on doctor’s visits and help make note of important details

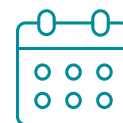
A few important reminders that can help:



Review the side effects carefully so you can help your loved one cope.



Reach out to their healthcare team with questions or concerns on their behalf.



Keep track of upcoming appointments, testing days, and milestones.



Remind them to take their medicine at the same time every day.

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PATIENT AND CAREGIVER RESOURCES

Take care of yourself while you're giving to others

Patients require a lot of support throughout their journey, and so do their caregivers. Many resources are available to help both of you feel supported.

PATIENT

Cancer Support Community

An international non-profit organization dedicated to uplifting and strengthening people impacted by cancer by providing support, fostering compassionate communities, and breaking down barriers to care.

www.cancersupportcommunity.org | 1-888-793-9355

PATIENT AND CAREGIVER

Leukemia & Lymphoma Society® (LLS)

An organization on the front lines of the fight to cure blood cancer. LLS is dedicated to research, patient access, and policy and advocacy. LLS has resources available for both patients and caregivers to help them in their journey with all blood cancers, including CML.

www.LLS.org/caregiverworkbook | 1-800-955-4572

National Comprehensive Cancer Network® (NCCN®)

NCCN has materials and NCCN Guidelines for Patients®.

Go to www.nccn.org to learn more.

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed May 7, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

PATIENT AND CAREGIVER RESOURCES (cont'd)

CAREGIVER

Caregiver Action Network

A non-profit organization devoted to improving the quality of life for family caregivers by providing education, peer support, and resources across the country.

www.caregiveraction.org | 1-855-227-3640

CAREGIVER

Well Spouse Association

Advocates for and addresses the needs of individuals caring for a chronically ill and/or disabled spouse or partner by offering peer support, education, and resources.

www.wellspouse.org | 1-732-577-8899

Learn more about CML

The following resources are available to anyone interested in additional information about CML:

American Cancer Society

1-800-227-2345

www.cancer.org

The National CML Society

www.nationalcmlsociety.org

CancerCare

1-800-813-4673

www.cancercare.org

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IMPORTANT FACTS

What is BOSULIF® (bosutinib)?

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.

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

Before you take BOSULIF, tell your doctor if you:

- have liver problems
- have heart problems
- have kidney problems
- have high blood pressure
- have diabetes
- are pregnant or plan to become pregnant. BOSULIF can harm your unborn baby. Tell your doctor right away if you become pregnant while taking BOSULIF
 - **Females** who are able to become pregnant should have a pregnancy test before starting treatment with BOSULIF and should use effective birth control (contraception) during treatment with BOSULIF and for at least 2 weeks 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 2 weeks after the last dose

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

These consumer important facts are based on BOSULIF patient information LAB-0443-16, October 2023.

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, vomiting, or blood in your stools. Get medical help right away for 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.** 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
- **Heart problems.** BOSULIF may cause heart problems, including heart failure and decreased blood flow to the heart, which can lead to heart attack. Get medical help right away if you get shortness of breath, weight gain, chest pain, or swelling in your hands, ankles, or feet
- **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. Get medical help 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.** 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

The most common side effects of BOSULIF in adults with CML include diarrhea, rash, nausea, stomach (abdomen) pain, vomiting, tiredness, liver problems, respiratory tract infections (infections in nose, throat, or lungs), fever, headache, constipation, and changes in certain blood tests. Your doctor may do blood tests during treatment with BOSULIF to check for changes.

Tell your doctor or get medical help right away if you get respiratory tract infections, loss of appetite, headache, dizziness, back pain, joint pain, rash, 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 both female and male patients. 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. You may report side effects to FDA at 1-800-FDA-1088.

REMINDERS TO MAKE THE MOST OF YOUR TREATMENT

Make sure to tell your healthcare team of any changes in:



Your prescription or any new medicines you start taking.



How you are feeling, even if you think it is not related to your CML.



Side effects, including ones that bother you or do not go away.



Your lifestyle, including any new health issues that may arise.

Start a routine



Take your medicine at the same time every day. Consider taking BOSULIF® (bosutinib) in the morning with breakfast or in the evening with dinner.



Quick Tip: Use the MyTherapy® app or another digital planner or calendar to set up daily reminders to take your medicine.



If you are prescribed BOSULIF capsules, store them in the original bottle.



DON'T MISS A DOSE -

SIMPLIFY MEDICATION REMINDERS

Scan the QR code to download the MyTherapy® app and set daily reminders

Your healthcare team can help you with side effects

When you start treatment, consider asking your doctor how to prepare for possible episodes of diarrhea, the most common side effect of BOSULIF.

- ↑ Dose adjustments from your doctor, lifestyle management,
- ↓ and monitoring over time may help you manage side effects.

Doctor's name: _____

Doctor's phone number: _____

Tips for managing side effects

The table below contains information about some common side effects of BOSULIF and tips that may help manage them. It's important to discuss this content with your healthcare team and set up a plan for managing any side effects you may have. Ask your healthcare team if there are over-the-counter or prescription medicines that may help you. Not all side effects are manageable. Your doctor may change your dose or tell you to stop taking BOSULIF.

DIARRHEA	✓ Hydrate: Drink lots of water ✗ Don't irritate: Eat mild foods. Avoid spicy, heavy, or sugary foods, and caffeine
NAUSEA OR VOMITING	✓ Eat smaller, more frequent meals ✓ Drink fluids in small amounts ✗ Avoid foods that are sweet, fried, or fatty
RASH	✓ Wear loose clothing ✗ Avoid soaking in long, hot baths
HEARTBURN/INDIGESTION	✓ Sleep in a more upright position, propped up on a pillow ✓ Reduce stress ✗ Avoid large meals, coffee, and alcohol
COUGH	✓ Eat well and drink plenty of fluids ✓ Suck on sore throat lozenges
FEVER	✓ Take medicine to control fever as recommended by your healthcare team
TIREDDNESS OR WEAKNESS	✓ 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
HEADACHE	✓ Increase self-care activities like sleep and meditation ✗ Limit alcohol intake

Please see a brief summary of **IMPORTANT FACTS** about BOSULIF on pages 4 and 5. [CLICK HERE](#) for full Prescribing Information including instructions for use.

 **Bosulif**[®]
bosutinib
tablets 500 mg | 400 mg | 100 mg
capsules 100 mg | 150 mg

IMPORTANT FACTS

What is BOSULIF® (bosutinib)?

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.

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

Before you take BOSULIF, tell your doctor if you:

- have liver problems
- have heart problems
- have kidney problems
- have high blood pressure
- have diabetes
- are pregnant or plan to become pregnant. BOSULIF can harm your unborn baby. Tell your doctor right away if you become pregnant while taking BOSULIF
 - **Females** who are able to become pregnant should have a pregnancy test before starting treatment with BOSULIF and should use effective birth control (contraception) during treatment with BOSULIF and for at least 2 weeks 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 2 weeks after the last dose

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

These consumer important facts are based on BOSULIF patient information LAB-0443-16, October 2023.

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, vomiting, or blood in your stools. Get medical help right away for 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.** 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
- **Heart problems.** BOSULIF may cause heart problems, including heart failure and decreased blood flow to the heart, which can lead to heart attack. Get medical help right away if you get shortness of breath, weight gain, chest pain, or swelling in your hands, ankles, or feet
- **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. Get medical help right away if you get any of the following symptoms during your treatment with BOSULIF:
 - shortness of breath and cough
 - swelling in your hands, ankles, or feet
 - weight gain
 - chest pain
 - swelling all over your body
- **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

The most common side effects of BOSULIF in adults with CML include diarrhea, rash, nausea, stomach (abdomen) pain, vomiting, tiredness, liver problems, respiratory tract infections (infections in nose, throat, or lungs), fever, headache, constipation, and changes in certain blood tests. Your doctor may do blood tests during treatment with BOSULIF to check for changes.

Tell your doctor or get medical help right away if you get respiratory tract infections, loss of appetite, headache, dizziness, back pain, joint pain, rash, 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 both female and male patients. 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. You may report side effects to FDA at 1-800-FDA-1088.

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capsules 100 mg | 50 mg