

Bosulif[®] bosutinib

ST_{PS}

Your guide
to treatment

Please see Important Safety Information for patients on pages 35-38.

Click for the full [Prescribing Information](#) and [Patient Information](#) or visit BOSULIF.com.

A complete resource

for adult patients taking BOSULIF 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. The approval of BOSULIF in newly diagnosed patients is based on molecular and cytogenetic response rates. There is an ongoing clinical study to confirm clinical benefit.

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

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Welcome

to the next STEP in your CML journey

BOSULIF[®] STEPS—resources for patients who are prescribed BOSULIF.

The goal of BOSULIF STEPS is to provide you with important information you can use throughout each step of your treatment. Whether this is your first time taking a medication for CML, or you have been treated in the past, this brochure will be a helpful resource to refer back to throughout treatment with BOSULIF[®] (bosutinib).



How should I use this brochure?

Throughout each section, you will notice that important terms have been **boldfaced**. All of these terms have been defined in an easy-to-use glossary on pages 39 and 40.

Also, you will find a worksheet at the end of this brochure. This worksheet contains tips to help manage common side effects, as well as space to write down any additional notes.



To learn more about how BOSULIF was studied, visit www.bosulif.com.

Why have I been prescribed BOSULIF?

BOSULIF is part of a group of medications called **tyrosine kinase inhibitors (TKIs)** used to treat adults who have a type of leukemia called Ph+ CML. It is not known if BOSULIF is safe and works in children less than 18 years of age.

Getting started on BOSULIF® (bosutinib)



Why am I starting BOSULIF?

BOSULIF is a treatment for:

Patients with **newly diagnosed** Ph+ CML, which means you are being treated for the first time.

Patients with Ph+ CML that is **resistant** to treatment, which means you no longer benefit from other treatment. Resistance is when your disease fails to respond or stops responding to a given therapy. It can occur at any time during treatment, even if you have been taking your medication for several years.

Patients who cannot tolerate their current treatment for Ph+ CML, which is when you can no longer take your current medicine due to unmanageable side effects.

It is possible for resistance or intolerance to occur with BOSULIF treatment.





The importance of taking BOSULIF as prescribed



Not taking your medicine as prescribed can impact how it works. It is important to take your medicine exactly as prescribed by your doctor.

Only your doctor can tell you if changes to your dosage are appropriate in managing your therapy.

See pages 16-18 for more tips that may help you take BOSULIF as your doctor prescribed.

Getting familiar with side effects of BOSULIF® (bosutinib) treatment



BOSULIF may cause a range of side effects. It's important to be familiar with the side effects so you know what may occur.

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

Getting familiar with side effects of BOSULIF® (bosutinib) treatment (cont'd)



BOSULIF may cause serious side effects, including:

- **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

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or online at www.fda.gov/MedWatch.

Getting familiar with side effects of BOSULIF® (bosutinib) treatment (cont'd)



BOSULIF may cause serious side effects, including:

- **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

Getting familiar with side effects of BOSULIF[®] (bosutinib) treatment (cont'd)

- **The common side effects of BOSULIF for those patients who are newly diagnosed include:** diarrhea, nausea, low platelet counts, rash, stomach pain, and changes in liver function tests
- **The common side effects of BOSULIF for those patients who no longer benefit from or did not tolerate other treatment include:** diarrhea, nausea, stomach pain, rash, low platelet counts, vomiting, low red blood cell counts, tiredness, fever, cough, headache, changes in liver function tests, and swelling
- 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



Remember to speak up

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 the FDA at 1-800-FDA-1088 or online at www.fda.gov/MedWatch.

Dealing with diarrhea



What are the most common side effects with BOSULIF?

In 2 **clinical studies** (newly diagnosed patients and patients who were treated before), the most common side effects associated with BOSULIF were stomach problems, including **diarrhea**. In the clinical trial of newly diagnosed patients, **70%** of patients experienced episodes of diarrhea while taking BOSULIF; in the clinical trial with patients resistant or intolerant to prior medicines, **85%** of patients experienced diarrhea while taking BOSULIF.

Diarrhea experienced by

Newly diagnosed patients:

Median^a length of time after starting treatment that diarrhea occurred

3 days

Patients who were treated before:

2 days

Newly diagnosed patients:

Median length of each episode of diarrhea

3 days

Patients who were treated before:

2 days

Newly diagnosed patients:

Percentage of patients with episodes of **severe** diarrhea

8%

Patients who were treated before:

9%

Reference: BOSULIF Prescribing Information. NY, New York: Pfizer Inc.

^aThe median is the "middle value" in a list of numbers. It is a kind of measurement. For example, the median number of episodes of diarrhea means that half of the patients in the study experienced more episodes of diarrhea, and half experienced fewer episodes of diarrhea.

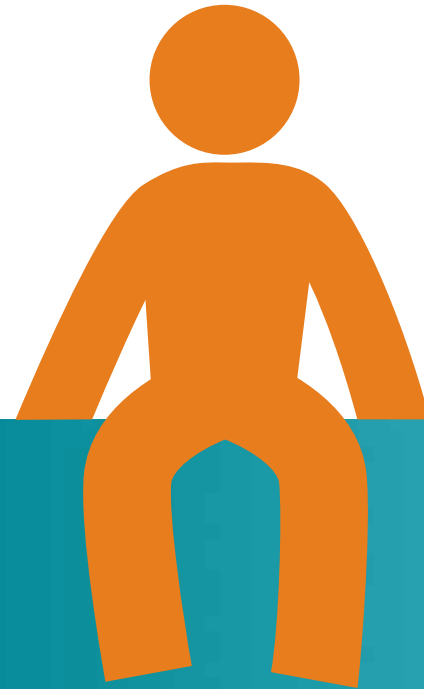
Dealing with diarrhea (cont'd)



What to do if you experience 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.



Tips to help manage diarrhea

It's a good idea to monitor what you eat and drink. You can discuss the following tips with your doctor:

- ✓ Eat mild foods
- ✓ Drink water often
- ✗ Avoid spicy foods, fatty foods, caffeine, and raw fruit

For more tips on managing side effects, see the side effects management sheet at the end of the brochure.

Talking to your doctor about other medications and conditions



What should I tell my doctor?

Your doctor needs to know about any other medical conditions or diseases that you have. In this section you'll learn about important items to discuss with your doctor.

Talking to your doctor about other medications and conditions (cont'd)

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.

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. 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 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



Talking to your doctor about other medications and conditions (cont'd)

Also let your doctor know about:

- Any changes in your medicines or any new medicines you start taking. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine
- Any side effect that bothers you or that does not go away
- Changes in your lifestyle, including any new health issues that may arise
- How you are feeling, even if you think it is not related to your CML

Ongoing communication can help you and your doctor work together to best manage your CML. Make sure you are following up with your doctor regularly, regardless of how you are feeling.

Tell your doctor about all the medications 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.



Taking BOSULIF[®] (bosutinib) as prescribed



How should I take BOSULIF?

It is important to take BOSULIF exactly as prescribed by your doctor. Follow the instructions below and talk with your doctor or nurse for more information.



BOSULIF is taken by mouth once a day



BOSULIF should be taken with food



Swallow BOSULIF tablets whole

- 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

Taking BOSULIF[®] (bosutinib) as prescribed (cont'd)



How should I take BOSULIF?

- Remember to always take BOSULIF exactly as prescribed. Do not change your dose or stop taking BOSULIF unless you are told to do so by your doctor
- Your doctor may change your dose of BOSULIF or tell you to stop taking BOSULIF depending on how you respond to treatment
- 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

Taking BOSULIF[®] (bosutinib) as prescribed (cont'd)



Tips to help you take BOSULIF as prescribed

- Make BOSULIF part of your daily routine by taking your medicine at the same time every day. It may help to take BOSULIF in the morning with breakfast or in the evening with dinner
- Organize your medicines with a pill container at home and when you travel
- Use alarms and calendars as reminders to take medication
- Keep a list of all the medicines you take, and tell your doctor before taking any new medicine
- If you are experiencing any side effects with BOSULIF, make sure to discuss them with your doctor

The importance of taking medicine as prescribed

It is important to take your medication as prescribed, because skipping doses or taking less medicine may affect your response to treatment. That's why it is very important to follow your doctor's instructions. If you ever have trouble taking your medicine or if you have questions about how much to take, talk with your doctor.



Red tablets are
500 mg



Orange tablets are
400 mg



Yellow tablets are
100 mg

Tablets are not shown at actual size.

The importance of taking medicine as prescribed (cont'd)



What is a dose adjustment?

BOSULIF is available in 500-, 400-, and 100-mg tablets, to allow for 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 change your dose of BOSULIF or tell you to stop taking BOSULIF, depending on how you are doing on treatment, as it may help manage side effects and response to treatment.



For more information or to learn more about Ph+ CML and the goals of treatment, visit www.bosulif.com.

Monitoring during therapy



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, and beyond. After *BCR-ABL1* 0.1%-1% (IS) has been achieved, molecular monitoring is recommended every 3 months for 2 years and every 3 to 6 months thereafter.^a

There are 3 types of responses that your doctor will measure to see if you are meeting treatment goals:

Types of responses in CML

Hematologic response	Cytogenetic response	Molecular response
A return of blood cell counts to normal levels, absence of immature cells in the blood outside of the bones	A decrease in the number of Philadelphia (Ph) chromosomes in bone marrow cells	A decrease in the percentage of blood cells containing <i>BCR-ABL</i> messenger ribonucleic acid (mRNA)

^aAdapted from NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Chronic Myeloid Leukemia v2.2018. © 2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines[®] and illustrations herein may not be reproduced in any form for any purpose without the express written permission of NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. The NCCN Guidelines are a work in progress that may be refined as often as new significant data becomes available. The 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.

Monitoring during therapy (cont'd)



A number of different types of tests will be performed throughout your CML therapy. Some of these tests help diagnose the disease, and others measure how well you are responding to treatment. Here you'll learn more about how these tests are important ways of evaluating your CML and your response to therapy.

Common laboratory tests done during CML treatment^a

Test	What it measures	What is needed
Quantitative polymerase chain reaction	The presence of very low levels of specific genetic material—in CML, QPCR measures the number of cells that have the <i>BCR-ABL</i> cancer gene	Blood or bone marrow sample
Fluorescence <i>in situ</i> hybridization (FISH)	Abnormal changes in a cell's genes and chromosomes, such as the presence of <i>BCR-ABL</i> and the Philadelphia (Ph) chromosome	Blood or bone marrow sample
Bone marrow cytogenetics	Cells carrying the Ph chromosome	Bone marrow sample

^aAdapted from NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Chronic Myeloid Leukemia v2.2018. © 2017 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines[®] and illustrations herein may not be reproduced in any form for any purpose without the express written permission of NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. The NCCN Guidelines are a work in progress that may be refined as often as new significant data becomes available. The 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.

Monitoring during therapy (cont'd)



Other tests during treatment with BOSULIF® (bosutinib)

A blood test called a complete blood count (CBC) is often done as part of a regular office visit to monitor your treatment with BOSULIF. A CBC counts the number of different kinds of cells in the blood.

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.

Your doctor should also 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.

Monitoring during therapy (cont'd)



Other health issues to monitor

It is very common for people to develop different kinds of health issues as they grow older, and it is important that you watch out for certain types of changes that could affect your health or your treatment.

If you have multiple medical conditions (called comorbidities), it is very important to have regular checkups to monitor these medical conditions and your overall health. These medical conditions may include:

- Heart disease
- Lung disease
- Other illnesses that may affect your body's ability to fight infection
- Kidney disease
- Diabetes

Remember, the more information your doctor has, the better he or she will be able to make decisions about what the best course of treatment is to manage your CML.

Treatment milestones



The following is a general set of recommendations for monitoring CML treatment that may be used for some patients. These are based on the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines in Oncology.^a

Follow-up point	Treatment goal
3 months	<i>BCR-ABL1</i> less than or equal to 10%, as detected by QPCR
6 months	<i>BCR-ABL1</i> less than or equal to 10%, as detected by QPCR
12 months	<i>BCR-ABL1</i> less than or equal to 1%, as detected by QPCR
Beyond 12 months	<i>BCR-ABL1</i> less than or equal to 0.1%, as detected by QPCR

^aReferenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia v2.2018. © National Comprehensive Cancer Network, Inc. 2017. All rights reserved. Accessed August 8, 2017. To view the most recent and complete version of the guideline, go online to NCCN.org. The 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.

Getting the support you need



In this section you will discover the patient services offered through Pfizer Oncology Together™.

✓ An extension of your support network

- **Specialty pharmacy** personnel are available 24/7 to offer assistance
- **Dedicated Care Champions** at Pfizer Oncology Together can guide you with resources that can make a difference in managing your day-to-day life, including nutrition information, help getting to and from your appointments, and connecting you with support groups so that you never feel alone

✓ Assistance with the cost of treatment

- **Pfizer Oncology Together** is here to help with co-pay support and financial assistance programs, regardless of your insurance coverage

✓ Resources and information

- **External resources** that you can turn to for peer support and disease education

Specialty pharmacies: An extension of your BOSULIF® (bosutinib) support network

Specialty pharmacies are similar to traditional pharmacies that you are used to, but they offer additional services for patients. This range of services includes:

- ✓ Prescriptions available by mail order and delivered to your home for added convenience
- ✓ Trained staff who are available to speak with you regarding delivery arrangements, side effects, and other treatment-related concerns
- ✓ Care team members who reach out to check on you when initiating treatment



BOSULIF is available through select specialty pharmacies



A current list of pharmacies is available at www.bosulif.com.



Specialty pharmacy contact



Pfizer Oncology Together will work with your healthcare provider to find a specialty pharmacy that is compatible with your insurance. For more information, please call 1-877-744-5675.

Financial support that can make a difference

Pfizer Oncology together™

If you need help understanding your insurance or what financial support may be available, our dedicated Care Champions are here to help—regardless of your insurance coverage.



COMMERCIALLY INSURED

Resources for eligible commercial, private, employer, and state health insurance marketplace patients.



Making sense of your coverage

We'll help you better understand your insurance coverage and benefits. Based on your coverage, we can refer you to the appropriate specialty pharmacy.



Co-pay assistance

Eligible, commercially insured patients may pay as little as \$0 for BOSULIF.*

Visit PfizerOncologyTogether.com or call **1-877-744-5675** (Monday-Friday 8 AM-8 PM ET) for live, personalized support.

*Limits, Terms, and Conditions apply. Patients may receive up to \$25,000 in savings annually.

The offer will be accepted only at participating pharmacies. This offer is not health insurance.

No membership fees apply. For full Terms and Conditions please see page 41. For any questions, please call **1-877-744-5675**, visit PfizerOncologyTogether.com, or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.



Financial support that can make a difference

Pfizer Oncology together™ (cont'd)



MEDICARE/GOVERNMENT INSURED

Help identifying resources for patients with Medicare/Medicare Part D, Medicaid, and other government insurance plans.



Making sense of your coverage

We'll help you better understand your insurance coverage and benefits. Based on your coverage, we can refer you to the appropriate specialty pharmacy.



Support from independent charitable foundations

Pfizer Oncology Together will assist you with searching for financial support that may be available from independent charitable foundations. These foundations exist independently of Pfizer and have their own eligibility criteria and application processes. Availability of support from the foundations is determined solely by the foundations.



Free medicine

We'll help determine if you're eligible to get BOSULIF for free through the Pfizer Patient Assistance Program.*

*The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation™. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc. with distinct legal restrictions.

 **Bosulif**®
bosutinib tablets
500 mg | 400 mg | 100 mg

Financial support that can make a difference

Pfizer Oncology together™ (cont'd)



UNINSURED

Help identifying resources for patients who do not have any form of healthcare coverage.



Help finding coverage

We can check to see if you're eligible for a government program that helps pay for prescription medicine through Medicaid or Medicare Part D.



Free medicine or savings

We can look into whether you're eligible to get BOSULIF free through the Pfizer Patient Assistance Program.*

Visit PfizerOncologyTogether.com or
call **1-877-744-5675** (Monday-Friday 8 AM-8 PM ET)
for live, personalized support.

*The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation™. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc. with distinct legal restrictions.

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Support beyond treatment



At Pfizer Oncology Together, we're here to help. Our Care Champions can guide you with resources that can make a difference in managing your day-to-day life, including nutrition information, help getting to and from your appointments, and connecting you to support groups so that you never feel alone. For problems big and small, you'll always have a place to turn.*



Financial support

Find options to help cover the cost of your medicine—regardless of your insurance coverage.



Support connections

Connect to local, community, and patient outreach programs that offer comfort and support.



Ongoing education

Get guidance on living with cancer, including tips on lifestyle, nutrition, and talking with loved ones.



Lodging and transportation

Learn about local programs that offer help with transportation or lodging while on treatment.



Custom check-ins

Schedule check-ins that work around you—offering support when you need it and want it.



Workplace guidance

Receive tools and support to help you prepare for leaving or returning to work after being diagnosed.



FOR LIVE, PERSONALIZED SUPPORT

Call **1-877-744-5676**

(Monday-Friday 8 AM-8 PM ET)

Visit PfizerOncologyTogether.com

*Some services are provided through third-party patient advocacy organizations.

Additional resources: Stepping away for more information

If you are looking for additional support or information, you can find external programs and networks below. Visit their websites or call directly with the phone numbers provided.

Cancer Support Community™

The Cancer Support Community is an international nonprofit dedicated to providing support, education, and hope to people affected by cancer.

www.cancersupportcommunity.org

Phone: 1-888-793-9355

Caregiver Action Network

The Caregiver Action Network provides education, peer support, and resources to family caregivers across the United States, free of charge.

www.caregiveraction.org

Phone: 1-202-454-3970

Patient Advocate Foundation

The Patient Advocate Foundation offers assistance to patients with specific issues they are facing with their insurer, employer, or creditors regarding insurance, job retention, or debt crisis matters relating to their diagnosis of life-threatening or debilitating disease.

www.patientadvocate.org

Phone: 1-800-532-5274

Well Spouse® Association

The Well Spouse Association advocates for and addresses the needs of individuals caring for a chronically ill and/or disabled spouse/partner.

www.wellspouse.org

Phone: 1-800-838-0879



Additional resources: Stepping away for more information (cont'd)

Learn more about CML

Leukemia & Lymphoma Society®

Phone: 1-800-955-4572

American Cancer Society®

Phone: 1-800-227-2345

The National CML Society

Phone: 1-877-431-2573

CancerCare®

Phone: 1-800-813-4673



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Important Safety Information that you should know



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 any other medical conditions
- 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 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

Important Safety Information that you should know (cont'd)



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

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

Important Safety Information that you should know (cont'd)



- **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

The common side effects of BOSULIF for those patients who are newly diagnosed include: diarrhea, nausea, low platelet counts, rash, stomach pain, and changes in liver function tests.

Important Safety Information that you should know (cont'd)



The common side effects of BOSULIF for those patients who no longer benefit from or did not tolerate other treatment include: diarrhea, nausea, stomach pain, rash, low platelet counts, vomiting, low red blood cell counts, tiredness, fever, cough, headache, changes in liver function tests, and 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 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 or online at www.fda.gov/MedWatch.

Please see Patient Information and full Prescribing Information.

Terms to know



BCR-ABL: An abnormal gene that causes bone marrow to grow white blood cells faster than normal.

Blast phase: The stage of CML when 20% or more of the cells in the blood or bone marrow are cancerous.

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

Chromosome: Part of a cell that holds genetic information.

Chronic phase: The phase of CML that most patients are diagnosed in. In this phase, less than 10% of the cells in the blood or bone marrow are cancerous.

Clinical study: A type of research study that tests how well a new medicine works in patients.

Cytogenetic response: A decrease in the number of Philadelphia (Ph) chromosomes in bone marrow cells.

Diarrhea: A common side effect in patients taking BOSULIF, when the bowels discharge frequent loose or watery stools.

- **Severe:** 7 or more loose or watery stools/bowel movements in 1 day

Gene: A piece of deoxyribonucleic acid (DNA) that parents pass on to a child. Genes determine hair and eye color, as well as many other traits.

Hematologic response: A return of blood cells to normal levels, absence of cancerous cells in the blood outside of the bones.

Terms to know (cont'd)



Intolerance¹: When a patient can no longer take his or her current medicine due to unmanageable side effects.

Median: The median is the “middle value” in a list of numbers. It is a kind of measurement. For example, the median number of episodes of diarrhea means that half of the patients in the study experienced more episodes of diarrhea, and half experienced fewer episodes of diarrhea.

Molecular response: A major molecular response means that the amount of *BCR-ABL* gene in your marrow is very low. A complete molecular response means that no *BCR-ABL* is detectable in the bone marrow.

Newly diagnosed: When a patient is being treated for his or her cancer for the first time.

Philadelphia chromosome: An abnormality in your genes that results in an unnatural protein called BCR-ABL. This gene causes CML cells to grow uncontrollably.

Resistant²: When your disease fails to respond or stops responding to a given therapy.

Tyrosine kinase inhibitor (TKI): A medicine that works to block CML cell growth in patients with cancer. In CML, a TKI is used to block BCR-ABL.

References: 1. Leukemia & Lymphoma Society. Chronic Phase CML Treatment. <http://www.lls.org/diseaseinformation/leukemia/chronicmyeloidleukemia/treatment/chronicphasecml>. Accessed May 19, 2017. 2. American Society of Clinical Oncology. Leukemia—Chronic Myeloid—CML. <http://www.cancer.net/cancer-types/leukemia-chronic-myeloid-cml/treatment-options>. Accessed May 19, 2017.

Terms and Conditions



By enrolling in the BOSULIF co-pay offer found on page 29, you acknowledge that you currently meet the eligibility criteria and will comply with the Terms and Conditions described below:

- This card is not valid for prescriptions that are eligible to be reimbursed, in whole or in part, by Medicaid, Medicare, Tricare or other federal or state healthcare programs (including any state prescription drug assistance programs) and the Government Health Insurance Plan available in Puerto Rico (formerly known as “La Reforma de Salud”).
- This card is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plans or other health or pharmacy benefit programs.
- With this card you will pay a \$0 co-pay per eligible monthly prescription, subject to a maximum benefit of \$25,000 per calendar year. The amount of any benefit is the difference between your co-pay and \$0. After the maximum of \$25,000 you will be responsible for the remaining monthly out-of-pocket costs. This card may be used once per 30 days until the maximum benefit has been reached. The average benefit is \$572.73 per patient per year.
- You must deduct the value of the benefit you receive with this card from any reimbursement request submitted to your insurance plan, either directly by you or on your behalf.
- This card is not valid where prohibited by law.
- Card cannot be combined with any other rebate/coupon, free trial or similar offer for the specified prescription.
- **Card will be accepted only at participating pharmacies.**
- **This card is not health insurance.**
- Offer good only in the U.S. and Puerto Rico.
- Card is limited to 1 per person during this offering period and is not transferable.
- Pfizer reserves the right to rescind, revoke or amend this offer without notice.
- No membership fee.
- Offer expires 12/31/2019.
- For reimbursement when using a nonparticipating pharmacy: 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 Co-Pay One Savings Card, to:

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

This sheet 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 doctor or nurse and set up a plan for managing any side effects you may have. Not all side effects are manageable. Your doctor may change your dose or tell you to stop taking BOSULIF.

Common side effects	Management tips to discuss with your doctor or nurse	Additional notes to track side effects
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 	
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 	

Indication

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. The approval of BOSULIF in these patients was based on molecular and cytogenetic response rates. There is an ongoing clinical study to confirm clinical benefit
- Who no longer benefit from or did not tolerate other treatment

Important Safety Information for patients

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 any other medical conditions
- 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 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 the medicines you take, including prescription medicines, nonprescription medicines, vitamins, and herbal supplements. BOSULIF and certain other medicines can affect each other.

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

The common side effects of BOSULIF for those patients who are newly diagnosed include: diarrhea, nausea, low platelet counts, rash, stomach pain, and changes in liver function tests.

The common side effects of BOSULIF for those patients who no longer benefit from or did not tolerate other treatment include: diarrhea, nausea, stomach pain, rash, low platelet counts, vomiting, low red blood cell counts, tiredness, fever, cough, headache, changes in liver function tests, and 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 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 or online at www.fda.gov/MedWatch.

Please see Patient Information and full Prescribing Information.

Click for the full [Prescribing Information](#) and [Patient Information](#) or visit BOSULIF.com.



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