



STARTING YOUR JOURNEY

with **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. 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

Please see important safety information on pages 4 and 5 and a brief summary of IMPORTANT FACTS about BOSULIF on the last page.



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

HOW TO USE THIS BROCHURE

In this brochure, you will find information that will help you:

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

When seeking specific information, use the tabs on the right to flip to the page you are looking for. Throughout, 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. 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 bone marrow to produce the leukemia cells.

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® (bosutinib) is a treatment for:

- **PATIENTS WITH NEWLY DIAGNOSED CHRONIC PHASE (CP) Ph+ CML**

This means you are being treated for the first time.

- **PATIENTS WITH Ph+ CML THAT IS RESISTANT TO TREATMENT**

This 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**

This means 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 works in children less than 18 years of age.

**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: 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

- **Stomach problems.** BOSULIF® (bosutinib) 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.** 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
- **Heart problems.** BOSULIF may cause heart problems, including heart failure. Get medical help right away if you get shortness of breath, weight gain 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

Please see important safety information on this page, page 5, and a brief summary of IMPORTANT FACTS about BOSULIF on the last page.

SIDE EFFECTS (cont'd)

- **Kidney problems.** BOSULIF® (bosutinib) 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 most 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 most 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 or get medical help 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.

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DEALING WITH DIARRHEA

Diarrhea

Most patients in the clinical studies of BOSULIF® (bosutinib) experienced diarrhea. 8% of patients who were newly diagnosed and 9% of patients with CP CML treated before experienced episodes of [severe diarrhea](#).

Before starting BOSULIF, ask your doctor or healthcare professional (HCP) how to prepare for possible episodes of diarrhea.

If you have diarrhea, call your doctor or HCP. Your doctor or HCP may recommend you take medicine to treat diarrhea. Always talk to your doctor before taking any over-the-counter medicines. Your doctor or HCP 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? ^b
Newly diagnosed patients	70%	Median of 3 days	Median of 3 days
Patients who were treated before	85%	Median of 2 days ^c	Median of 2 days ^c

^aMedian length of time after starting treatment that diarrhea occurred. (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.)

^bMedian length of each diarrhea episode.

^cIncludes advanced phase patients.

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.

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MANAGEMENT TIPS FOR POTENTIAL SIDE EFFECTS

The table below contains information about some common side effects of BOSULIF® (bosutinib) 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. Ask your doctor or healthcare provider (HCP) 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 and avoid spicy and fatty foods, raw fruit, 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"> ✓ Drink warm fluids with honey and lemon ✓ Suck on sore throat lozenges
FEVER	<ul style="list-style-type: none"> ✓ Take medicine to control fever as recommended by your HCP
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"> ✗ Limit alcohol intake



QUICK TIP: USE A JOURNAL TO TRACK HOW YOU'RE FEELING

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

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bosutinib tablets
500 mg | 400 mg | 100 mg

HOW SHOULD I TAKE BOSULIF?

BOSULIF® (bosutinib) is available in 400-mg, 500-mg, and 100-mg tablets and is taken once a day with food



Tablets not shown at actual size.

Your doctor or healthcare professional (HCP) most likely started you on a dosing schedule of taking one 400-mg tablet a day if you are newly diagnosed or one 500-mg tablet a day if you were resistant or intolerant to prior therapy. 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 OR HCP CAN TELL YOU IF CHANGING YOUR DOSE IS APPROPRIATE IN MANAGING YOUR THERAPY

What is a dose adjustment?

BOSULIF is available in 400-mg, 500-mg, and 100-mg tablets to allow for dose adjustments. A dose adjustment is when your doctor or HCP changes the amount of BOSULIF you're taking in order to best tailor your therapy to your individual needs. Your doctor or HCP 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.

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MAKE SURE TO TAKE BOSULIF AS PRESCRIBED

When you take BOSULIF...

WHAT TO DO



Take BOSULIF exactly as prescribed by your doctor



Take BOSULIF 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



- 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

WHAT NOT TO DO



DO NOT change your dose or stop taking BOSULIF without first talking to your doctor.



DO NOT crush, break, or cut BOSULIF tablets. Do not touch or handle crushed or broken BOSULIF tablets.



DO NOT take a proton pump inhibitor (PPI) medicine without talking to your doctor or pharmacist first.



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 consume grapefruit, grapefruit juice, and supplements that contain grapefruit extract. Grapefruit products increase the amount of BOSULIF in your body.

TERM TO KNOW

Proton pump inhibitor: A substance used to treat certain disorders of the stomach and intestines, such as heartburn and ulcers.

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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 number of cells that have the *BCR-ABL* cancer gene.* qPCR-International Scale (IS) is how many *BCR-ABL* cells you have in your blood compared to baseline. After *BCR-ABL* 0.1%-1% has been achieved, 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 percentage of blood cells containing <i>BCR-ABL</i>

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

qPCR milestones	
	100% of baseline Your <i>BCR-ABL</i> cell 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 ≤10% of when you started treatment
- MMR is major molecular response, which means the amount of *BCR-ABL* is ≤0.1% of what it was at baseline

*Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Myeloid Leukemia V.2.2020. © National Comprehensive Cancer Network, Inc. 2019. All rights reserved. Accessed October 23, 2019. 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.

WHAT ELSE SHOULD BE MONITORED DURING TREATMENT?

Your doctor may also 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 doctor or healthcare professional (HCP) of any changes in:



Your medicines 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.



Use alarms and calendars as reminders to take medicine.



Use a pill container to organize your medicines at home and when you travel.

Your doctor or HCP 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™

Patient Support. Financial Assistance. Together.

Financial Assistance



Commercially insured

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

- Co-pay assistance: Eligible, commercially insured patients may pay as little as \$0 per month for BOSULIF*

***Limits, terms, and conditions apply.** 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 \$25,000 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 full Terms and Conditions, please see PfizerOncologyTogether.com/terms. 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.

At Pfizer Oncology Together, our Care Champions, who have social work experience, can offer you resources that may help with some of your day-to-day challenges†:

Emotional Support

Find resources for emotional support and other daily challenges. These resources include support groups, an independent organization's helpline, and a free app designed to help you connect with loved ones.

Transportation and Lodging

Connect to an independent organization that helps eligible patients find rides and lodging for treatment-related appointments.

Workplace Guidance

Receive information to help you prepare for leaving or returning to work after being diagnosed.

Ongoing Education

Get guidance on living with your condition, including nutritional information, communication tips, and toolkits specific to your prescribed medicine.

Financial Support

Get help identifying financial assistance resources—regardless of your insurance coverage.

†Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.



FOR LIVE, PERSONALIZED SUPPORT

Call **1-877-744-5675** (Monday-Friday 8 AM-8 PM ET)

VISIT

PfizerOncologyTogether.com

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FOR CAREGIVERS: HELPING YOUR LOVED ONE THROUGHOUT THEIR JOURNEY

When a loved one has Ph+ CML, there are many things you can do to help them through their disease and treatment. Use the information in this brochure to help them with:

- Understanding their disease and treatment
- Creating a routine with BOSULIF® (bosutinib)
- Managing potential side effects

You can make a difference in your loved one's treatment

Reminders about treatment, emotional support, and accompanying your loved one when talking to healthcare professionals (HCPs) can help make your loved one's journey with BOSULIF easier.

Use the following reminders to help your loved ones:



Review the tips for managing side effects so you know how to help them cope



Help them reach out to their doctor or HCP if they have questions or concerns



Record appointments and testing dates and remind them as they approach



Remind them to take their treatment at the same time every day

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Take care of yourself while you're giving to others

There are resources available that are designed specifically for people like you, so you always feel supported.

Leukemia & Lymphoma Society®

LLS has a Caregiver Workbook as a resource to help you support your loved ones. Call an information specialist with questions or to request a workbook.

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

Caregiver Action Network

Provides education, peer support, and resources to caregivers across the United States, free of charge.

www.caregiveraction.org | 1-202-454-3970

Well Spouse Association

Advocates for and addresses the needs of individuals caring for a chronically ill and/or disabled spouse/partner.

www.wellspouse.org | 1-800-838-0879

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ADDITIONAL RESOURCES TO GET YOU THE SUPPORT YOU NEED

The external programs and networks below offer additional support on your treatment journey

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. It has resources available for both patients and caregivers to help them in their journey with Ph+ CML.

www.LLS.org/CaregiverWorkbook 1-800-955-4572

Cancer Support Community

An international nonprofit organization dedicated to providing support, education, and hope to people affected by cancer.

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

National Comprehensive Cancer Network® (NCCN®)
NCCN has materials and NCCN Guidelines for Patients®.
Go to www.nccn.org to learn more.

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**
1-877-431-2573
www.nationalcmlsociety.org

CancerCare
1-800-813-4673
www.cancercare.org

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IMPORTANT FACTS

WHAT IS BOSULIF® (bosutinib)?

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- Who no longer benefit from or did not tolerate other treatment

WHO SHOULD NOT TAKE BOSULIF?

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

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING 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 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, nonprescription 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-0639-10.0, October 2019.

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.** 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
- **Heart problems.** BOSULIF may cause heart problems, including heart failure. Get medical help right away if you get shortness of breath, weight gain 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
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 - you urinate more or less often than normal
 - you make a much larger or smaller amount of urine than normal

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The most 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.

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The risk information provided here is not comprehensive. To learn more, talk to your healthcare provider about BOSULIF. To obtain the full Prescribing Information including Patient Information visit www.bosulif.com or call 1-877-744-5675.