



Your guide to **TREATMENT** with BOSULIF[®] (bosutinib)

You can report any side effects that you may get to the HPRA Pharmacovigilance. Website: www.hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

Contents

INDICATIONS¹

BOSULIF[®] is indicated for the treatment of adult patients with:

- Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukaemia (Ph+ CML)
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options



About this guide	3
Introduction to BOSULIF[®]	5
What is BOSULIF [®] ?	
Why have I been prescribed BOSULIF [®] ?	5
Symptoms of CML	6
How can I get the most out of treatment with BOSULIF[®]?	7
What dose of BOSULIF [®] should I take?	
How do I take BOSULIF [®] ?	8
Remember to take your BOSULIF [®] tablets	9
What about other medicines I am taking with BOSULIF [®] ?	10
Dealing with possible side effects	11
What are the possible side effects associated with BOSULIF [®] ?	
Diarrhoea	12
Nausea (feeling sick) or vomiting	15
Skin rash or itchy skin	15
Fatigue (tiredness)	16
Possible serious side effects	17
Changes in your liver function	
Low blood count (low number of blood cells)	19
Changes in your kidney function	19
Abnormal electrical signals in the heart	20
Other warnings and precautions	20
Getting the support you need	21
General resources and information	
Getting the most out of clinic visits	22
Reporting of side effects	23
Recording how you feel when taking BOSULIF [®]	
Glossary	45
References	47
Notes	48

About this guide



This guide will:

- Provide you with information about treating chronic myeloid leukaemia (CML) with BOSULIF[®].
 - Help you manage any side effects that you may experience while you are taking BOSULIF[®].
 - Help you find further sources of information, support and advice. The information provided in this brochure does not replace discussion with your doctor about your disease and your treatment. Please follow the instructions provided by your doctor carefully and read the BOSULIF[®] patient leaflet.²
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Reporting of side effects. Different people sometimes respond in different ways to the same product or medicine, and some side effects may not be discovered until many people have used a medicine over a period of time. If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can report any side effects that you may get to the HPRA Pharmacovigilance. Website: www.hpra.ie; E-mail medsafety@hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.



Introduction to BOSULIF[®]

What is BOSULIF[®]?

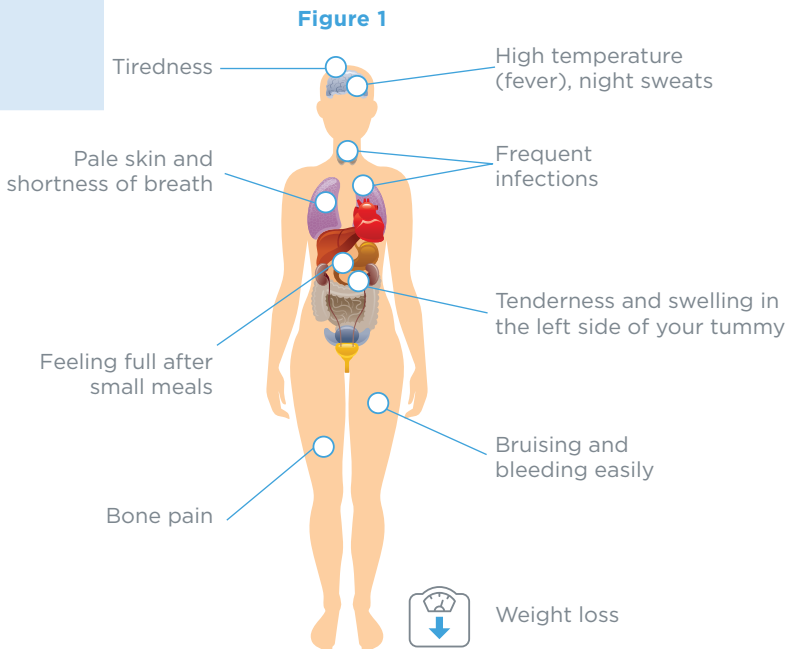
- BOSULIF[®] contains the active substance bosutinib.^{1,2}
- It is used to treat adults who have a type of leukaemia called Philadelphia chromosome-positive (Ph-positive) Chronic Myeloid Leukaemia (CML).^{1,2}
- Ph-positive CML is a cancer of the blood that makes the body produce too many of a specific type of white blood cell called granulocytes.^{2,3}

Why have I been prescribed BOSULIF[®]?

- BOSULIF[®] has been tested in over 1,300 patients in clinical trials. It is used to treat adults with Ph-positive CML who are either newly diagnosed or for whom previous medicines have either not worked or proven unsuitable.¹
- Your doctor has given you BOSULIF[®] because they feel it is the most appropriate medicine for you at this point in your CML treatment.

Symptoms of CML⁴

CML doesn't usually have any symptoms in its early stages and may only be picked up during tests carried out for another reason. As the condition develops, symptoms can manifest (Figure 1).





How can I get the most out of treatment with BOSULIF®?

What dose of BOSULIF® should I take?

- Your doctor will prescribe you the appropriate dose for your condition.
- In most cases, the starting dose of BOSULIF® is either 400 mg (if you have been newly diagnosed) or 500 mg (if previous medicines have either not worked or proven unsuitable for you) once a day, taken with food.^{1,2}
- During treatment, your doctor may adjust your dose depending on your medical conditions, your response to treatment and/or any side effects that you may experience.²
- Your doctor will tell you the right dose to take. Don't increase or decrease your dose of BOSULIF®, or stop treatment, without talking to them first.

Please always use the dose recommended by your doctor, which may be different from the usual starting dose.

How do I take BOSULIF®?^{1,2}

Check the labels of foods and drinks to make sure they don't contain grapefruit products. These foods may increase the levels of BOSULIF® in your body and increase the chance of side effects.

- Take the BOSULIF® tablet(s) with food at the same time every day, such as with breakfast.
- Swallow the tablet(s) whole with water.
- Do not take BOSULIF® with grapefruit or grapefruit juice.



TIPS TO HELP YOU REMEMBER:

Try taking your BOSULIF[®] tablet(s) at the same time every day, such as with your breakfast. The routine may help you to remember.

Use reminders such as:

- A weekly medication dose box.
- Phone alarms.
- Ask a friend or family member to remind you to take your medication.
- Leave a sticky note on the fridge.
- Set a recurring SMS reminder on your phone.
- Apps are available to download to your Smartphone to help remind you to take your medication.

Take your BOSULIF[®] tablets as recommended by your doctor.²

Remember to take your BOSULIF[®] tablets

It is important to take BOSULIF[®] every day because:

- Taking your medicine every day as recommended by your doctor **will give you the best chance of responding to BOSULIF[®] and controlling your CML.**
- If you regularly forget to take your medicine, it **could affect how well your CML is controlled.**

Your doctor might have good reasons to pause your treatment to manage side effects. **Do not stop taking BOSULIF[®] or miss any doses of your medicine** unless this has been discussed with your doctor first.²

**IF YOU FORGET TO TAKE BOSULIF²**

- If a dose is missed by less than 12 hours, take your recommended dose as soon as possible.
- If a dose is missed by more than 12 hours, take your next dose at your regular time on the following day.
- **DO NOT** take a double dose to make up for a dose you have missed.

IF YOU ARE CONSIDERING STOPPING BOSULIF²

- Don't stop taking BOSULIF[®] without talking to your doctor first.
- If you feel unable to take the medicine as your doctor prescribed, or you feel you do not need it anymore, contact your doctor straight away.

IF YOU TAKE MORE BOSULIF[®] THAN YOU SHOULD²

- Contact your doctor straight away.

What about other medicines I am taking with BOSULIF[®]?^{1,2}

- Tell your doctor or nurse if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription, vitamins and herbal medicines.
- Before starting any new medications (including antibiotics and antifungals), you should discuss this with your doctor first. Some medicines, including herbal medicines, can affect the levels of BOSULIF[®] in your body, or should not be taken with BOSULIF[®] for other reasons.
- Some examples of medicines that should be avoided, or that should be taken with caution while receiving BOSULIF[®], are listed on pages 41 and 42 of this guide (Tables 1 and 2). Please also refer to the Patient Information Leaflet² contained in your BOSULIF[®] pack for further information. Your doctor may change the dose of these medicines, change the dose of BOSULIF[®], or switch you to a different medicine.



Dealing with possible side effects

What are the possible side effects associated with BOSULIF®?

Like all medicines, BOSULIF® can cause side effects, although not everybody gets them.²

A list of side effects that could occur while taking BOSULIF® are provided in Table 3 on pages 43 and 44 and in the Patient Information Leaflet² contained in your BOSULIF® pack.

Talk to your doctor if you experience any side effects. This includes any possible

side effects not listed in this guide or the Patient Information Leaflet.²

The most common side effect of BOSULIF® is diarrhoea.¹

Nausea (feeling sick), vomiting, abdominal pain, skin rash, fatigue (tiredness), blood and liver disorders are other common side effects associated with BOSULIF®.^{1,2}



TOP TIPS FOR DIARRHOEA

- If you develop diarrhoea, **treat it as soon as possible with loperamide**,⁵ a common treatment for diarrhoea.
- You can buy loperamide over the counter from most pharmacies, or your doctor can prescribe it for you.
- Follow the dosage instructions carefully, and do not exceed the recommended dosage.
- It is **very important to drink plenty of liquids** to replace those lost through diarrhoea. Your doctor may recommend rehydration fluids.⁵

Diarrhoea

Diarrhoea is an increase in the number of stools (bowel movements) per day above your normal level.²

Diarrhoea is a very common occurrence, especially during the first few days and weeks of treatment with BOSULIF®.^{1,6}

Diarrhoea with BOSULIF® normally goes away with time.⁶

Contact your doctor/nurse or pharmacist if you develop diarrhoea that persists or worsens over time.²

It is important to manage your diarrhoea early to prevent you from becoming dehydrated and so it does not interfere with your daily routine.⁶



Tips for eating and drinking during periods of diarrhoea

If you develop diarrhoea, think about adapting your diet:

Drink 8–10 cups of fluid daily⁷

These could include:⁷

- Water (flavoured or plain).
- Ginger ale.
- Sports drinks.
- Weak decaffeinated teas.
- Caffeine-free soft drinks, but let carbonated drinks lose their fizz.



Eat 5 or 6 small meals a day instead of 3 large ones^{6,7}

Eat low-fibre, starchy food and food that is high in sodium (salt) and potassium^{6,7}

(when you have diarrhoea, your body loses these substances, and it is important to replace them):

Foods high in potassium include bananas and potatoes.

Try low-fibre, starchy foods, such as white toast, rice and plain pasta.



Avoid food or drinks that make diarrhoea worse⁷

These include:

- Foods high in fibre, such as wholegrain bread and cereals, green peas, beans and lentils.
- Spicy, fatty or fried foods.
- Foods and drinks that can cause gas. Examples include cooked dried beans and raw vegetables.
- Food and drinks that are very hot or very cold.



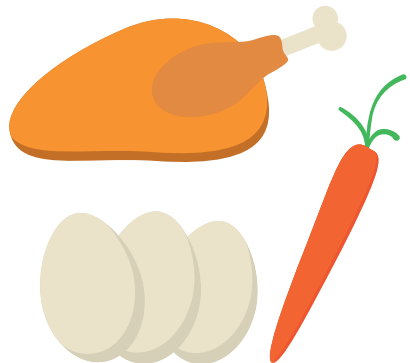
TELL YOUR DOCTOR

- If your diarrhoea persists or worsens, or if you develop constipation – but **DO NOT** stop taking your medicine.²
- If you are taking medicines that may promote diarrhoea, such as laxatives, stool softeners or other stomach medicines. Your doctor may ask you to stop taking these.⁸
- If you have stomach pain or cramps. Your doctor may give you a medicine that can help.



WHEN SYMPTOMS IMPROVE, TRY EATING FOODS THAT ARE GENTLE ON YOUR STOMACH. THESE INCLUDE:

- Plain or vanilla yoghurt.
- Eggs.
- Fish.
- Skinless chicken or turkey.
- Tender, well-cooked vegetables, especially carrots, string beans and mushrooms that are low in fibre.
- Canned fruits.





Nausea (feeling sick) or vomiting



TOP TIPS FOR NAUSEA OR VOMITING

- Tell your doctor immediately if you **feel sick or are vomiting**.²
- Your doctor can prescribe medicines that may help you.²

Tips for eating to help manage nausea⁷

BOSULIF[®] should be taken with food.^{1,2}

- Do not miss meals; an empty stomach can make nausea worse.⁷
- Try to eat small meals and snack frequently, avoid mixing very hot or very cold food and drink together.⁶
- Eat foods that appeal to you.⁶
- Try to eat foods that are gentle on the stomach.⁶
- Eat dry toast or crackers before you get out of bed if your nausea is bad in the morning.⁷

Eat foods that are gentle on your stomach, such as:⁷

- White toast, noodles and plain pasta.
- Plain or vanilla yoghurt.
- Soups (avoid those made from foods that cause gas, such as dried beans, peas, broccoli and cabbage).
- Beef (tender cuts) or skinless chicken and turkey.
- Bananas and canned fruit, such as peaches and pears.

Drink small amounts at meal times as too much fluid can make you feel bloated.⁷

Vomiting may increase the risk of dehydration. If you experience vomiting, take small sips of water once it has stopped to replace the fluids you have lost.⁹

Skin rash or itchy skin



TOP TIPS FOR SKIN RASHES

- Tell your doctor or nurse if you develop a **skin rash or itchy skin**.²
- For mild rash or itching, there are fragrance-free emollient (moisturising) creams, medicated creams and other medicines available from your pharmacy that can help.¹⁰
- Tell your doctor if you **develop a red or purplish rash that spreads and blisters**, and/or if anything appears in your mouth or on your lips.²



If you develop a skin rash, you may also find the following tips helpful:

- Avoid clothing that is made from wool, synthetics or other harsh materials.¹⁰
- Avoid ointments (e.g. those containing mineral oil or petroleum), harsh soaps containing detergents, scented products such as creams, bubble baths, deodorants and perfumes, and water that is too hot, as they can irritate the skin.¹⁰
- Use mild soaps for sensitive skin, wear loose-fitting cotton clothes,¹⁰ and use cotton bedding.

Fatigue (tiredness)

- Tiredness can be caused by many things, including your CML or treatment.¹¹ Your doctor can help identify possible causes of your tiredness and treat them.

- There are support services that your doctor can recommend if you are feeling tired.
- Do not drive or operate machines if you feel unusually tired, experience dizziness or have blurred vision, until you feel better.²

If you are feeling more tired than usual, you may find the following tips helpful:



TOP TIPS FOR TIREDNESS

- Have an active daily routine.¹¹
- **Regular light exercise** may help if you are feeling tired.¹¹
- **Try to be as active as you can during the day but:**¹¹
 - If you need a nap, take a short one so that it doesn't affect your sleep at night.
 - Plan most important activities or high-energy tasks when your energy levels are highest.
- Don't be afraid to ask someone to help you.¹¹
- **Take your mind off your tiredness:**¹¹
 - Play games, read or listen to music.

Tell your doctor if tiredness is bothering you.



Possible serious side effects

Changes in your liver function

- Mild liver function changes are common, but usually occur without symptoms. Your doctor will do blood tests regularly to see if BOSULIF[®] is affecting your liver.¹
- Tell your doctor if you have, or have had in the past, liver problems including hepatitis.²
- Your doctor may pause your treatment or reduce the dose of BOSULIF[®] if there are signs that treatment is affecting your liver function.¹



TOP TIPS TO MANAGE CHANGES IN YOUR LIVER FUNCTION

- Tell your doctor if you have a history of liver disease and if you have, or have ever had, a hepatitis B infection.²
- If your liver function tests have changed, you should avoid medicines and other substances that may affect the liver, such as **alcohol or paracetamol**.
- Ask your doctor which pain-relief medicine you should use instead of paracetamol if you develop a headache or have pain elsewhere.
- **Tell your doctor** if you are taking any herbal medicines. Some over-the-counter **herbal medicines** may also reduce the effectiveness of BOSULIF.² For example, it has been shown that kava, a herb that has been used to help with stress and anxiety, may cause liver damage.¹²

Sometimes, but not often, liver disorders are serious

Contact your doctor straight away if you develop any of the following symptoms, which can be signs of a serious liver disorder:²

- Itching.
- Yellowing of the whites of the eyes or skin.
- Dark urine.
- Pain or discomfort in the upper abdomen, on the right-hand side of your body.
- Fever.



Low blood count (low number of blood cells)

As with all medicines for CML, BOSULIF[®] can reduce your blood count, which is the number of blood cells you have in a sample of your blood.²

- **Red blood cells** carry oxygen and help with your energy levels.
- **Platelets** help your blood to clot, which stops bleeding.
- **White blood cells** help you fight infections.

Your doctor will regularly monitor your blood count using a blood test.

- If your blood count is low, your doctor may give you other treatments, pause your treatment with BOSULIF[®], or reduce the dose of BOSULIF[®] to help your blood count recover.¹
- **Contact your doctor** straight away if you develop any of the following signs that might be associated with a low blood count:²
 - Bleeding.
 - Fever.
 - Easy bruising.

Changes in your kidney function

BOSULIF[®] can affect your kidneys, reducing their ability to filter waste products from the blood.

Reduced kidney function is mainly caused by a decrease in the rate at which blood is filtered in the kidneys.

Your doctor will do regular urine and blood tests to see if BOSULIF[®] is affecting your kidneys.

- If your renal function has decreased, your doctor may prescribe a reduced dose of BOSULIF[®].¹
- However, depending on your response to treatment, your doctor may later adjust the dose of BOSULIF[®],^{1,2} even if your kidney function is reduced.
- **Contact your doctor** straight away if you develop any of the following symptoms, which might be associated with reduced kidney function:²
 - Vomiting and/or diarrhoea.
 - Nausea.
 - Weight loss.
 - Pain in your side.
 - Swelling of your feet, ankles, legs, hands or face.
 - Abnormal amounts of urine (greater or smaller quantities).
 - Blood in the urine.

Abnormal electrical signals in the heart

Your doctor will monitor the electrical activity of your heart, using a test called an electrocardiogram (ECG).¹

- **Contact your doctor** straight away if you develop any of the following symptoms, which may be due to a heart problem:²
 - Irregular heartbeat.
 - Fainting/loss of consciousness.

Sun/UV protection

You may become more sensitive to the sun or UV rays while taking bosutinib. It is important to cover sunlight-exposed areas of skin and use sunscreen with high sun protection factor (SPF).

Other warnings and precautions²

Talk to your doctor before taking BOSULIF[®]:

- If you have signs of infection including fever, problems with urine such as burning on urination, a new cough, or a new sore throat.
- If you have signs and symptoms of fluid retention such as swelling of the ankles, feet and legs; difficulty breathing; chest pain or a cough.
- If you have, or have had, pancreas problems, including if you develop abdominal pain or discomfort.
- If you have a serious skin rash including a painful red or purplish rash that spreads and blisters and/or other lesions that begin to appear on the mouth or lips.



Getting the support you need

General resources and information

For confidential advice, support and information, you can speak to an Irish Cancer Society nurse by contacting their Support Line on Freephone 1800 200 700.

IRISH CANCER SOCIETY DAFFODIL CENTRES are located in thirteen hospitals nationwide. The centres are staffed by cancer nurses and trained volunteers who provide free, confidential advice, support and information to anyone affected by cancer. To find your nearest Daffodil Centre, visit www.cancer.ie/support/daffodil-centres.

Speak to your doctor, nurse or pharmacist as they will advise you on specific patient groups or additional sources of information that you may find useful.

*Pfizer has no oversight over or input into any third party patient group materials.



Getting the most out of clinic visits

You should meet regularly with your doctor to:

- Check how well you are responding to BOSULIF® treatment.
- Talk about any side effects that you may have experienced.
- Receive ongoing support.
- These meetings are your opportunity to ask your doctor any questions you may have.
- Try writing a list of questions you want to ask before you go to see your doctor. Make a note of the most important questions, and ask them first in case you run out of time.
- It may help you to keep a note of side effects as you experience them. An example of how to do this can be found on the next page. Take your list of side effects and questions to your next appointment, so you don't forget to discuss them.
- Take a pen and paper or this booklet with you. You can write down what your doctor or nurse tells you. This will help you remember what was discussed, and you can refer back to it later if you need to.



Reporting of side effects

Recording how you feel when taking BOSULIF[®]

There are many ways of recording how you feel when taking BOSULIF[®]. Find something that works for you.

Try keeping a record of any side effects that you experience, when they happened and how bad they were on a scale of 1 (mild) to 10 (severe). A weekly treatment diary has been provided to help you with this. See pages 25 to 40.

**REPORTING OF SIDE EFFECTS.**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRa Pharmacovigilance, Website: www.hpra.ie. Any suspected adverse reactions may also be reported to Pfizer Medical Information on 1800 633 363.

The following pages will help you record any side effects that you experience while receiving your treatment with BOSULIF® so that you can discuss these with your doctor, pharmacist or nurse.

Depending on the nature and severity of the side effects you experience, your treatment may need to be paused, reduced or discontinued.

It is therefore important that you talk to your doctor about any side effects that you experience.













Week 1

Current dose:

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
 No symptoms							
 Diarrhoea, vomiting, stomach pain, nausea							
 Fever, swelling of hands, feet or face							
 Infection, common cold, cough							
 Fatigue							
 Decrease in appetite							
 Pain (joints, back, muscle)							
 Headache							
 Skin rash							
 Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	













Week 2

Current dose:

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
 No symptoms							
 Diarrhoea, vomiting, stomach pain, nausea							
 Fever, swelling of hands, feet or face							
 Infection, common cold, cough							
 Fatigue							
 Decrease in appetite							
 Pain (joints, back, muscle)							
 Headache							
 Skin rash							
 Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	













Week 3

Current dose:

		Mon	Tue	Wed	Thu	Fri	Sat	Sun
	No symptoms							
	Diarrhoea, vomiting, stomach pain, nausea							
	Fever, swelling of hands, feet or face							
	Infection, common cold, cough							
	Fatigue							
	Decrease in appetite							
	Pain (joints, back, muscle)							
	Headache							
	Skin rash							
	Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	













Week 4

Current dose:

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
 No symptoms							
 Diarrhoea, vomiting, stomach pain, nausea							
 Fever, swelling of hands, feet or face							
 Infection, common cold, cough							
 Fatigue							
 Decrease in appetite							
 Pain (joints, back, muscle)							
 Headache							
 Skin rash							
 Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	



REPORTING OF SIDE EFFECTS











Week 5

Current dose:

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
 No symptoms							
 Diarrhoea, vomiting, stomach pain, nausea							
 Fever, swelling of hands, feet or face							
 Infection, common cold, cough							
 Fatigue							
 Decrease in appetite							
 Pain (joints, back, muscle)							
 Headache							
 Skin rash							
 Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	













Week 6

Current dose:

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
 No symptoms							
 Diarrhoea, vomiting, stomach pain, nausea							
 Fever, swelling of hands, feet or face							
 Infection, common cold, cough							
 Fatigue							
 Decrease in appetite							
 Pain (joints, back, muscle)							
 Headache							
 Skin rash							
 Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	













Week 7

Current dose:

		Mon	Tue	Wed	Thu	Fri	Sat	Sun
	No symptoms							
	Diarrhoea, vomiting, stomach pain, nausea							
	Fever, swelling of hands, feet or face							
	Infection, common cold, cough							
	Fatigue							
	Decrease in appetite							
	Pain (joints, back, muscle)							
	Headache							
	Skin rash							
	Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	



REPORTING OF SIDE EFFECTS











Week 8

Current dose:

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
 No symptoms							
 Diarrhoea, vomiting, stomach pain, nausea							
 Fever, swelling of hands, feet or face							
 Infection, common cold, cough							
 Fatigue							
 Decrease in appetite							
 Pain (joints, back, muscle)							
 Headache							
 Skin rash							
 Shortness of breath							



Week beginning: ____ / ____ / ____

Notes	
	
	
	
	
	
	
	
	
	
	

**Table 1: Medicines that should be avoided during treatment with BOSULIF^{1,2}**

If you are taking any of them, tell your doctor. Your doctor may change the dose of these medicines, change the dose of BOSULIF[®] or switch you to a different medicine.

Medicine	Used for the treatment of	Potential side effect
Ketoconazole, itraconazole, voriconazole, posaconazole, fluconazole	Fungal infections	May increase side effects with BOSULIF [®]
Clarithromycin, telithromycin, erythromycin, ciprofloxacin	Bacterial infections	
Nefazodone	Depression	
Mibefradil, diltiazem, verapamil	High blood pressure	
Ritonavir, lopinavir/ritonavir, indinavir, nelfinavir, saquinavir, atazanavir, amprenavir, fosamprenavir, darunavir	HIV/AIDS	
Boceprevir, telaprevir	Hepatitis C	
Aprepitant	Nausea (feeling sick) and vomiting	
Rifampicin	Tuberculosis	May reduce the effectiveness of BOSULIF [®]
Phenytoin, carbamazepine	Epilepsy	
Bosentan	High blood pressure in the lungs	
Nafcillin	Bacterial infections	
St. John's Wort	Depression (non-prescription medication)	
Efavirenz and etravirine	HIV/AIDS	
Modafinil	Sleep disorders	

The medicines listed here may not be the only ones that could interact with BOSULIF[®].



Table 2: Medicines that should be taken with caution during your treatment with BOSULIF^{1,2}

If you are taking any of them, tell your doctor.

Medicine	Used for the treatment of	Potential side effect
Amiodarone, disopyramide, procainamide, quinidine, sotalol	Heart disorders	May affect heart rhythm
Chloroquine, halofantrine	Malaria	
Clarithromycin and moxifloxacin	Bacterial infections	
Haloperidol	Psychotic disease such as schizophrenia	
Domperidone	Nausea (feeling sick) and vomiting Stimulating breast milk production	

The medicines listed here may not be the only ones that could interact with BOSULIF®.

**Table 3: Potential side effects that you may experience while receiving BOSULIF^{1,2}**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see last box, Table 3). By reporting side effects, you can help provide more information on the safety of this medicine.

Very common side effects ^a	
Reduction in the number of platelets, red blood cells and/or neutrophils (type of white blood cells)	Decrease in appetite
Diarrhoea, vomiting, stomach pain, nausea	Joint or back pain
Fever, swelling of hands, feet or face, fatigue, weakness	Headache
Respiratory tract infection	Skin rash (which may be itchy and/or generalised)
Nasopharyngitis	Cough
Changes in your blood tests to determine if Bosulif is affecting your liver and/or pancreas, kidneys	Shortness of breath
Feeling of instability (dizziness)	Fluid in the lungs (pleural effusion)
Itching	

Common side effects ^a	
Low white blood cell count (leukopenia)	Alteration of the sense of taste (dysgeusia)
Stomach irritation (gastritis), bleeding from the stomach or intestine	Acute kidney failure, kidney failure, kidney impairment
Chest pain, pain	Fluid around the heart (pericardial effusion)
Toxic damage to the liver, abnormal hepatic function including liver disorder	ringing in the ears (tinnitus)
Infection of the lung (pneumonia), influenza, bronchitis	Urticaria (hives), acne
Defect in cardiac rhythm that predisposes to fainting, dizziness and palpitation	Photosensitivity reaction (sensitivity to UV rays from the sun and other light sources), allergic reaction
Increase in blood pressure	Allergic reaction
High level of potassium in the blood, low level of phosphorus in the blood, excessive loss of body fluid (dehydration)	Abnormally high blood pressure in the arteries of the lungs (pulmonary hypertension).
Pain in the muscles	Respiratory failure
Acute inflammation of the pancreas (acute pancreatitis)	

^aFrequency categories are defined as: very common (may affect more than 1 in 10 people), common (may affect up to 1 in 10 people), uncommon (may affect up to 1 in 100 people), and not known (frequency cannot be estimated from the available data).



Uncommon side effects^a

Fever associated with low white blood cell count (febrile neutropenia)	A marked decrease in the number of granulocytes (a type of white blood cells)
Damage to the liver	Severe skin disorder (erythema multiforme)
Life-threatening allergic reaction (anaphylactic shock)	Nausea, shortness of breath, irregular heartbeat, muscular cramps, seizure, clouding of urine and tiredness associated with abnormal laboratory test results (high potassium, uric acid and phosphorous levels and low calcium levels in the blood) that can lead to changes in kidney function and acute renal failure –(Tumour lysis syndrome (TLS)).
Abnormal build-up of fluid in the lungs (acute pulmonary oedema)	
Skin eruption	
Inflammation of the sac-like covering of the heart (pericarditis)	

Not known (frequency cannot be estimated from the available data)^a

Severe skin disorder (Stevens-Johnson syndrome, toxic epidermal necrolysis) due to an allergic reaction, exfoliative (scaly, peeling) rash
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^aFrequency categories are defined as: very common (may affect more than 1 in 10 people), common (may affect up to 1 in 10 people), uncommon (may affect up to 1 in 100 people), and rare (may affect up to 1 in 1000 people).

GLOSSARY

Antibiotics	Medications prescribed to treat infection
Antifungals	Medication used to treat fungal infections, which most commonly affect your skin, hair and nails
Blood count	A measure of the number of red blood cells, white blood cells and platelets in the blood. It is used to help diagnose and monitor many conditions
Bosutinib	The active ingredient in BOSULIF [®] . This belongs to a group of medicines that target cancer cells
Chronic myeloid leukaemia (CML)	CML is a cancer of the blood that makes the body produce too many of a specific type of white blood cell called granulocytes
Constipation	A reduction in the number of stools (bowel movements) per day above your normal level or stools that are difficult to pass or larger than usual
Diarrhoea	An increase in the number of stools (bowel movements) per day above your normal level
Dose modifications	A dose reduction is a decrease in your prescribed dose in response to a side effect. A dose increase is an increase in your prescribed dose once the side effect has passed or due to being unresponsive to current dose. Doses are modified in 100 mg steps, up or down
Electrocardiogram (ECG)	A line graph that shows changes in the electrical activity of the heart over time. It can also show abnormal conditions, such as blocked arteries, changes in electrolytes and changes in the way electrical currents pass through the heart tissue
Electrolyte	A substance that carries an electrical charge when it is dissolved in water or body fluids. Examples include sodium, potassium, calcium, chloride and phosphate
Emollient/ointments	Moisturising treatments applied directly to the skin to soothe and hydrate it, often used to help manage dry, itchy or scaly skin conditions
Fatigue	A condition marked by extreme tiredness and inability to function due to lack of energy. Fatigue may be acute or chronic
Granulocytes	A type of white blood cell with a role in fighting infection
Hepatitis	A disease characterised by infection or inflammation of the liver
Hepatitis B	Hepatitis B is an infection of the liver caused by a virus spread through blood and body fluids
Herbal medicines	Medicines with active ingredients made from plant parts, such as leaves, roots or flowers, but as with conventional medicines, will have an effect on the body and can be potentially harmful if not used correctly

Leukaemia	Leukaemia is a cancer that starts in blood-forming tissue, usually the bone marrow. It leads to the over-production of abnormal white blood cells, the part of the immune system that defends the body against infection. There are different types of leukaemia and the treatment you need depends on the type. CML is one type of leukaemia
Nausea	A feeling of sickness or discomfort in the stomach that may come with an urge to vomit
Philadelphia chromosome-positive (Ph-positive)	Patients possess an abnormal chromosome called the Philadelphia chromosome. This is created from pieces of two different chromosomes combining. The Philadelphia chromosome contains a gene that results in the development of CML
Platelets	A type of blood cell that helps your body form clots and stop bleeding
Red blood cells	A type of blood cell responsible for transporting oxygen around the body
Renal function	Renal function tests are used to determine if your kidneys are performing appropriately
Resistance or intolerance	<p>In the context of previous CML treatment:</p> <p>Resistance – you are no longer receiving benefit from taking the drug, i.e. your condition is deteriorating</p> <p>Intolerance – the side effects associated with the treatment become too severe to continue therapy</p>
Side effect	An unwanted effect of taking your prescribed treatment that is unrelated to the primary function of the drug
Tyrosine kinase inhibitor	A type of cancer drug that blocks the function of tyrosine kinases and blocks the growth of cancer cells
Vitamins	Nutrients your body needs in small amounts to work properly and stay healthy. Most people obtain all the nutrients they need by having a varied and balanced diet, although some people may need to take extra supplements
Vomiting	The process of ejecting some or all of the contents of the stomach through the mouth
White blood cells	A type of blood cell that is made in the bone marrow and found in the blood and lymph tissue. White blood cells are part of the body's immune system, and they help the body to fight infection and other diseases

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