

YOUR GUIDE TO TREATMENT WITH

imbruvica[®]
(ibrutinib)



YOUR KEY CONTACTS

Haematologist/Haematology

Registrar name: _____

Phone: _____

Nurse name: _____

Phone: _____

Pharmacy: _____

Phone: _____

Hospital: _____

Switchboard: _____

ADDITIONAL CONTACT INFORMATION

Name: _____

Phone: _____

Relationship: _____

Name: _____

Phone: _____

Relationship: _____



imbruvica®
(ibrutinib)

ABOUT THIS BOOKLET

It's normal to need some extra support to help you cope with the emotional and practical issues of illnesses such as CLL, MCL or WM and their treatment. There are many ways to seek support, and it's important to find the ones that best suit you.

This booklet was developed to support people prescribed IMBRUVICA (ibrutinib). It will help you, and your family and friends, understand more about your condition and what you can expect during your treatment. It also suggests how to access extra support.

THE INFORMATION IN THIS BOOKLET IS NOT DESIGNED TO REPLACE THE ADVICE OF YOUR DOCTOR OR HEALTHCARE TEAM. IF YOU HAVE ANY CONCERNS OR FURTHER QUESTIONS, PLEASE DON'T HESITATE TO TALK TO YOUR DOCTOR OR CANCER CARE NURSE.



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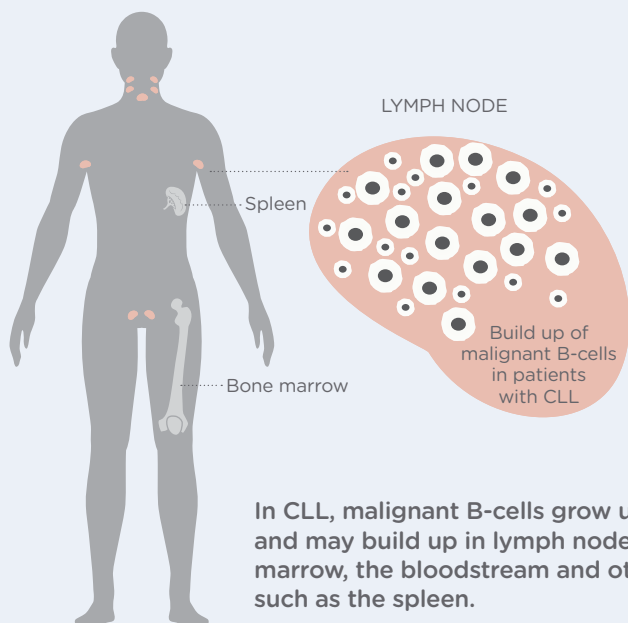
ABOUT YOUR BLOOD CANCER

WHAT ARE CLL AND SLL?

Chronic lymphocytic leukaemia (CLL) is a slow-growing cancer that affects developing B-cells (also known as B-lymphocytes) in the blood and bone marrow.

B-cells are a type of white blood cell that help protect you from infection and disease. In people with CLL, malignant (cancerous) B-cells multiply in an uncontrolled way. The malignant B-cells do not work properly to fight disease, and live longer than healthy B-cells. Over time, excess malignant B-cells crowd the bone marrow and interfere with the body's ability to produce healthy blood cells, which can lead to anaemia, bleeding disorders and recurring infections.

Small lymphocytic lymphoma (SLL) is also a slow-growing cancer affecting B-cells. In SLL, malignant B-cells are found mostly in the lymph nodes rather than the blood. Due to similarities in the cancers and the way they are treated, CLL and SLL are usually coupled together and referred to as CLL/SLL.



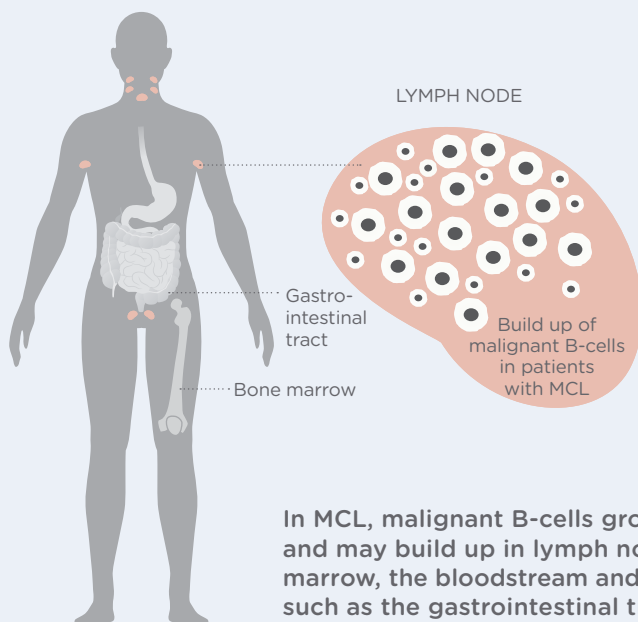
In CLL, malignant B-cells grow uncontrollably and may build up in lymph nodes, bone marrow, the bloodstream and other organs such as the spleen.

WHAT IS MCL?

Mantle cell lymphoma (MCL) is a rare non-Hodgkin lymphoma that affects the lymphatic system.

In MCL, malignant, uncontrolled B-cells build up to form abnormal clusters of cancer cells in lymph nodes and other parts of the body. The condition is called mantle cell because these high concentrations of cancer cells are found in the 'mantle zone' – the outer edge – of the lymph nodes.

MCL is usually fast-growing. Which organs are affected and how the condition develops vary from person to person.

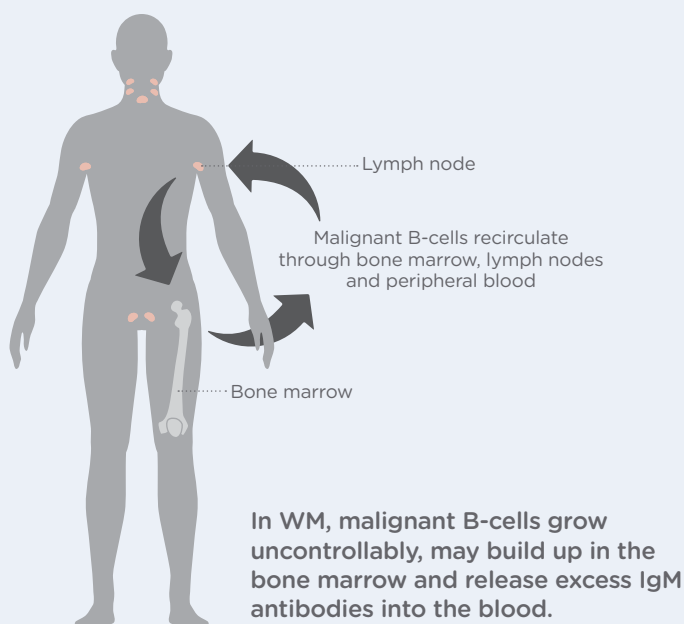


In MCL, malignant B-cells grow uncontrollably and may build up in lymph nodes, bone marrow, the bloodstream and other organs such as the gastrointestinal tract.

WHAT IS WM?

Waldenstrom's macroglobulinaemia (WM) is a rare, slow-growing non-Hodgkin lymphoma that affects the lymphatic system.

Excess malignant B-cells crowd the bone marrow and interfere with the body's ability to produce healthy blood cells. In people with WM, malignant B-cells also produce large amounts of abnormal IgM antibodies, which can make the blood become thicker and difficult to flow.



ABOUT IMBRUVICA

YOU HAVE BEEN PRESCRIBED IMBRUVICA TO HELP CONTROL YOUR BLOOD CANCER.

IMBRUVICA is a 'targeted' medicine that blocks the growth and spread of CLL/SLL, MCL or WM.

IMBRUVICA targets an enzyme called Bruton's tyrosine kinase (or BTK). BTK enables B-cells to live and grow. In blood cancer, this function is uncontrolled, allowing B-cells to stay alive and keep dividing.

By binding to BTK, IMBRUVICA inhibits the function of BTK while leaving healthy cells relatively unaffected. IMBRUVICA therefore may help kill and reduce the number of cancerous B-cells and control disease.






ASK YOUR DOCTOR OR HEALTHCARE PROFESSIONAL IF YOU HAVE ANY QUESTIONS ABOUT IMBRUVICA OR WHY IT HAS BEEN PRESCRIBED FOR YOU.

TAKING IMBRUVICA

HOW MUCH IMBRUVICA TO TAKE

How much IMBRUVICA you should take will depend on your diagnosis and your doctor's recommendations.

As a guide, recommended IMBRUVICA doses are:

	CLL/SLL 1 x 420 mg tablet	ONCE A DAY
	MCL 1 x 420 mg and 1 x 140 mg tablet	ONCE A DAY
	WM 1 x 420 mg tablet	ONCE A DAY

- Always take your IMBRUVICA exactly as your doctor or pharmacist has told you
- If you are taking multiple IMBRUVICA tablets, take them all at the same time – do not space them out over the day
- Do not change your dose or stop taking IMBRUVICA unless your doctor tells you to do so



HOW TO TAKE IMBRUVICA



Swallow the tablets whole with a glass of water. Do not open, break or chew them



Take the tablets at about the same time each day. It doesn't matter what time of day you take IMBRUVICA, so choose a time that you are most likely to remember and take it at that time every day



You can take IMBRUVICA with or without food



Do not take IMBRUVICA with grapefruit or Seville oranges, including any juice or supplements that may contain them – they can affect the amount of IMBRUVICA in your blood

TAKING IMBRUVICA

HOW LONG TO TAKE IMBRUVICA

Unlike some chemotherapy treatments that you receive at intervals for a few weeks or months, IMBRUVICA is taken every day. This is because it only works when it's in your body, and it needs to be replaced with a new dose every day.

CONTINUE TO TAKE IMBRUVICA EVERY DAY, EVEN IF YOU DO NOT HAVE ANY SYMPTOMS OR YOUR CONDITION SEEMS TO HAVE IMPROVED. DO NOT CHANGE YOUR DOSE OR STOP TAKING IMBRUVICA UNLESS YOUR DOCTOR TELLS YOU TO.

TIPS FOR REMEMBERING YOUR IMBRUVICA EVERY DAY

Try to fit taking IMBRUVICA into your daily routine:

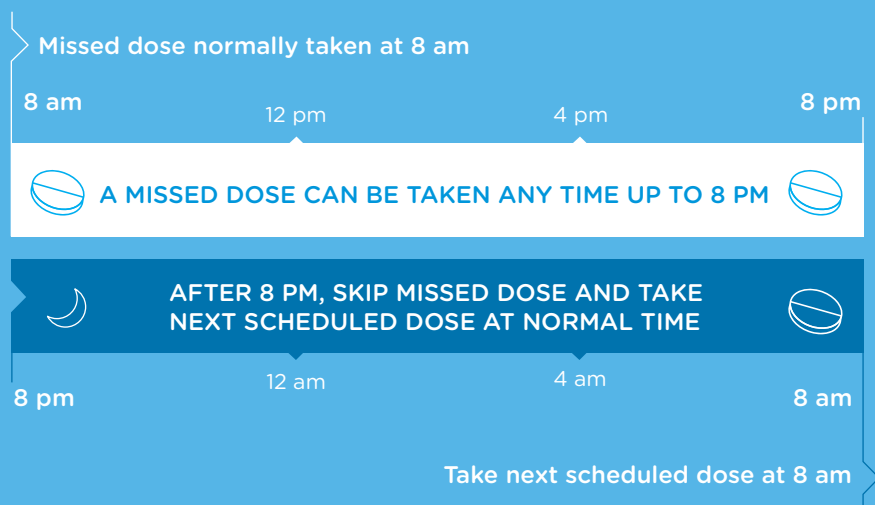
- Link it to something else you do every day, like brushing your teeth or having a morning coffee
- Set a daily alarm on your watch, phone or clock
- Put a reminder note or your medicine container somewhere you will see it (but out of the sight and reach of children)
- Ask a family member or friend to remind you



WHAT IF I MISS A DOSE?

- If there are more than 12 hours until your next scheduled dose, take the missed dose as soon as possible, then continue with your next dose of IMBRUVICA at your usual time
- If your next scheduled dose is due in less than 12 hours, skip the missed dose and take the next scheduled dose at the usual time
- Do not take a double dose to make up for a missed dose
- If you miss a dose and are not sure what to do, talk to your doctor, pharmacist or nurse about when to take your next dose

EXAMPLE - WHAT TO DO IF YOU MISSED A DOSE AT 8 AM



TAKING IMBRUVICA

WHAT IF I TAKE TOO MUCH?

If you take more than the recommended dose of IMBRUVICA, contact your doctor, pharmacist or the National Poisons Centre, who will advise you what to do.

- National Poisons Centre: 0800 764 766

CAN I TAKE OTHER MEDICINES WITH IMBRUVICA?

IMBRUVICA can interact with some medicines. This may stop the medicines working properly, or lead to side effects.

IT'S IMPORTANT TO TELL YOUR DOCTOR IF YOU ARE TAKING ANY OTHER MEDICINES, INCLUDING MEDICINES YOU CAN BUY WITHOUT A PRESCRIPTION FROM A PHARMACY, SUPERMARKET OR HEALTH FOOD SHOP. YOUR DOCTOR CAN TELL YOU WHETHER YOU CAN CONTINUE THE MEDICINES YOU ARE TAKING OR CHANGE THE DOSE.

HOW TO STORE IMBRUVICA

- Store IMBRUVICA below 30°C in the original container
- Do not store it in the bathroom or near the sink
- Keep all medicines out of the sight and reach of children
- Do not use this medicine after the expiry date, which is stated on the carton and foil strip after 'EXP'

DURING TREATMENT WITH IMBRUVICA

HOW DO I KNOW IF I'M RESPONDING TO MY TREATMENT?

Your doctor will monitor you regularly to check how you are responding to treatment. This may include physical examinations, blood tests and other tests such as scans and biopsy.

UNDERSTANDING YOUR TESTS

Your doctor may ask for tests to be carried out during your treatment with IMBRUVICA. Some common tests include:

BLOOD TESTS

Samples of your blood will be taken regularly throughout your treatment to check your general health, the levels of red blood cells, white blood cells – particularly your lymphocyte counts – and platelets in your blood, and how well your liver and kidneys are working. Your doctor uses these test results to monitor how your CLL or MCL is affecting your body and how your body is tolerating treatment.

ECG

Cancer treatments can sometimes make your heartbeat irregular. If you have symptoms such as palpitations (racing, fluttering or pounding heartbeat), chest discomfort, or new onset of breathlessness, dizziness, or fainting, your doctor will check your heartbeat with an ECG (short for electrocardiogram). Up to 12 leads are placed against your skin with sticky tape while you lie on an examination couch. A small machine then assesses how your heart is working by measuring its electrical activity. The process takes approximately 5 minutes.



Ask a member of your healthcare team to explain why you need the tests and what the results mean.



WHAT IS LYMPHOCYTOSIS?

Lymphocytosis is an abnormal increase in the number of lymphocytes in the blood.

IMBRUVICA changes the way cancer cells move around the body; it makes cancer cells move from lymph nodes (where they normally multiply) into the bloodstream (where they do not grow). During the first few weeks of treatment, your blood tests may show an increase in cancer cells in your blood (lymphocytosis). This is expected, and may last for a few months.

In rare cases, the increase in white blood cells may be severe, and cause cells to clump together. This is called leukostasis. Your doctor will monitor your blood to check for this rare effect, and may treat you with other medicines or ask you to temporarily stop taking IMBRUVICA.

DURING TREATMENT WITH IMBRUVICA

AVOIDING INFECTIONS DURING IMBRUVICA TREATMENT

People being treated for blood cancers may pick up infections easily – make sure you do your bit to protect yourself.



Wash your hands regularly with soap and water. Be sure to wash your hands:

- Before, during and after you prepare food
- Before you eat
- After you use the toilet
- After being in a public place
- After blowing your nose, coughing or sneezing
- After you touch an animal, animal food or animal waste
- After you touch household waste



Practise good food hygiene, cook/chill foods properly and avoid foods that could contain harmful bacteria such as raw eggs and shellfish.



Be careful around people. If you know that someone has a fever, cold, flu, or any other infection, stay away from them until they feel better.

POSSIBLE SIDE EFFECTS WITH IMBRUVICA

Like all medicines, IMBRUVICA can cause side effects, although not everybody gets them. Common side effects with IMBRUVICA include:

- Bruises
- Constipation
- Decreased appetite
- Diarrhoea
- Dizziness
- Fainting
- Feeling very tired
- Fever
- Headache
- Infected nose, sinuses or throat
- Muscle and joint pain
- Nausea or vomiting
- Shortness of breath
- Skin rash
- Swollen hands, ankles or feet

Please don't be alarmed by this list of possible side effects – remember you may not experience any of them. Take a look at the IMBRUVICA Consumer Medicine Information leaflet if you would like to find out more about possible side effects.

Do not stop taking IMBRUVICA unless your doctor asks you to, unless you think you may be having an allergic reaction (see following page).



Tell your doctor, pharmacist or nurse if you have any side effects, including any that are not listed in this booklet.

MORE INFORMATION ABOUT SPECIFIC SIDE EFFECTS

ALLERGIC REACTION

If you notice an itchy bumpy rash, difficulty breathing, swelling of your face, lips, tongue or throat – you may be having an allergic reaction to the medicine.

- Stop taking IMBRUVICA and tell a doctor straight away

BLEEDING

You may experience bruising or nosebleeds during treatment with IMBRUVICA. In rare cases, serious internal bleeding, such as bleeding in your stomach, intestine, or brain may occur.

- Call your doctor or healthcare professional if you have signs or symptoms of serious bleeding, such as blood in your stools or urine, or bleeding that lasts for a long time or that you cannot control
- Let your doctor know if you are planning to have any surgery, as you may need to stop taking IMBRUVICA for a short time before and after your surgery

DIARRHOEA

Tell your doctor or healthcare professional if you develop symptoms of uncontrolled diarrhoea. If you have diarrhoea that lasts for more than a week, your doctor may need to give you a fluid and salt replacement or another medicine.

HEART PROBLEMS

Tell your doctor or healthcare professional if you have any heart problems, or if you develop symptoms such as chest discomfort, palpitations, or new onset of breathlessness, dizziness, or fainting.

INFECTIONS

You may experience viral, bacterial, or fungal infections during treatment with IMBRUVICA. See page 17 for what you can do to help protect yourself from infections.

- Contact your doctor if you have fever, chills, body aches, cold or flu symptoms, feel tired or feel short of breath – these could be signs of an infection
- Your doctor may monitor your blood counts and treat you with other medicines

LIVER PROBLEMS

You may experience changes in liver function while on treatment with IMBRUVICA, although this is a very rare complication. Your doctor will monitor your liver function in periodic blood tests.

- Call your doctor immediately if you notice signs of jaundice, such as yellowing of the whites of your eyes

OTHER CANCERS

New cancers have occurred in people taking IMBRUVICA, including skin cancer and other cancers.

- Be sun smart – cover your skin to protect it from sun damage

FATIGUE/DIZZINESS

You may feel very tired or dizzy after taking IMBRUVICA

- Do not drive or use any tools or machines if you are feeling tired or dizzy

EATING WELL

People living with blood cancer can benefit from a diet that is rich in protein and energy (calories). If your body doesn't get enough protein and energy from food, it may use your own muscle for the fuel it needs. A healthy diet provides the nutrients your body needs, and can help increase your energy levels, maintain your strength, manage side effects of treatment and improve your mood.

MAKE EVERY MOUTHFUL MEANINGFUL, BY MAKING SURE THAT EVERY MEAL, EVERY SNACK AND EVERY FLUID GIVES YOU USEFUL NUTRIENTS

CHOOSING HEALTHY FOODS CAN BE EMPOWERING AND MAKE A BIG DIFFERENCE TO YOUR WELLBEING

Although there is a huge amount of online information available about eating well, it can be challenging to separate evidence-based food facts from misinformation and myths. People living with cancer can be particularly susceptible to misinformation about so-called 'cancer-cure' diets, superfoods and supplements.

The best way to get tailored information about which foods are best for you is to talk to an Accredited Practising Dietitian.



Talk to your doctor before taking any vitamins, minerals or natural supplements, as they have the potential to interact with the medications you are taking, including IMBRUVICA

STAYING ACTIVE

Many people receiving cancer treatment feel unsure about whether exercise is for them. But research shows that exercise not only improves your strength and fitness levels, it can also help reduce disease symptoms, minimise side effects of treatment and improve overall wellbeing for people with cancer.¹ Surprisingly, exercise can even help reduce cancer-related fatigue!

LINKING EXERCISES TO EVERYDAY ACTIVITIES CAN HELP MAKE EXERCISE PART OF YOUR LIFESTYLE

WHAT KIND OF PHYSICAL ACTIVITY IS RIGHT FOR ME?

All people living with cancer should stay as active as possible. A personal exercise program tailored to your specific abilities and preferences may help you get the most from your efforts. An accredited exercise physiologist or physiotherapist with experience in cancer care can help you decide what's right for you.

Ask your doctor (GP or haematologist) or haematology nurse for advice on where to get support for developing an exercise program.



Check with your healthcare team before starting any new exercise program.

1. Courneya K *et al.* Randomized Controlled Trial of the Effects of Aerobic Exercise on Physical Functioning and Quality of Life in Lymphoma Patients. *J Clin Oncol* 2009;27:4605-4612.



SETTING WELLNESS GOALS

It can be really challenging to make changes in your life, especially when you are coping with cancer treatment. The process of goal-setting gives you the opportunity to reflect on what is important to you, giving you clarity about what you want to achieve and how you want to do it.

Make sure you choose goals that are meaningful to you. It may help to think about different areas of your life such as social, intellectual, physical, emotional, occupational or spiritual aspects, and focus on one or two that are important. Consider breaking down your overall goals into manageable chunks that are achievable, and plan out what you need to do to get there.

CELEBRATE YOUR SUCCESSES AND REWARD YOURSELF FOR MAKING CHANGES

Everyone has good days and bad days, and you may not always be able to achieve what you set out to do. Just take it one day at a time and reset from the beginning if you need to.

RESOURCES

Living with a blood cancer can be challenging, but there are a range of support services available to you.

The following organisations are a good place to start. They provide reliable information as well as emotional or practical support, and are available to cancer patients across New Zealand.

LEUKAEMIA BLOOD CANCER NEW ZEALAND

www.leukaemia.org.nz/

0800 15 10 15

CLL ADVOCATES NEW ZEALAND

clladvocates.nz/

CANCER SOCIETY OF NEW ZEALAND

www.cancer.org.nz/

0800 226 237



NOTES

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NOTES

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IMBRUVICA® (ibrutinib) Capsules and Tablets

Information for consumers

IMBRUVICA is a Prescription Medicine. Your doctor will advise you if IMBRUVICA may be suitable for you. IMBRUVICA has risks and benefits. Always read the label and use strictly as directed. If symptoms continue, or if you experience side effects, contact your doctor, pharmacist or health professional.

IMBRUVICA is used to treat patients with Mantle cell lymphoma (MCL) who have received at least one prior therapy, Chronic lymphocytic leukaemia (CLL) and Waldenström's macroglobulinemia (WM).

The usual daily dose of IMBRUVICA for CLL and WM is 420 mg as a single dose. The usual daily dose of IMBRUVICA for MCL is 560 mg taken as a single dose. IMBRUVICA capsules and tablets should be swallowed whole with water. Do not take IMBRUVICA with grapefruit juice or Seville oranges. Your doctor may choose to also combine IMBRUVICA with other medicines.

Each IMBRUVICA capsule contains 140 mg of ibrutinib and is supplied in bottles containing either 90 or 120 capsules. Each IMBRUVICA tablet may contain 140 mg, 280 mg, 420 mg or 560 mg of ibrutinib. IMBRUVICA 140 mg tablets are supplied in cartons containing 30 or 120 tablets.

IMBRUVICA 280 mg, 420 mg and 560 mg tablets are supplied in cartons containing 30 tablets. IMBRUVICA should be stored below 30°C.

Do not take IMBRUVICA if you are pregnant or maybe potentially pregnant. Do not breast feed.

Before taking IMBRUVICA you must tell your doctor:

- If you have problems with your liver or kidneys
- If you have ever had unusual bruising or bleeding or are on any medicines or supplements that increase your risk of bleeding
- If you have a history of high blood pressure, irregular heartbeat (atrial fibrillation, ventricular tachyarrhythmia), heart failure or diabetes
- If you have recently had or are planning to have any surgery
- If you have or have had Hepatitis B infection
- If you have any other medical condition

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Please read the Consumer Medicine Information for the full list of side effects. Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given IMBRUVICA.

Common side effects of IMBRUVICA may include: diarrhoea; indigestion; feeling very tired; nausea; headache; swollen hands, ankles or feet; being short of breath; dizziness; fainting; inflamed and sore mouth; infected nose, sinuses or throat (cold); high blood pressure; irregular heart beat; urinary tract infections; infection; cough; trouble sleeping; anxiety; discharge with itching of the eyes and crusty eyelids; blurred vision; constipation; fever; vomiting; decreased appetite; bruises; nose bleed; red or purple, flat, pinhead spots under the skin; skin rash; muscle spasm; muscle and joint pain; sore stomach; low blood sodium or potassium; changes in your platelet, white or red blood cell levels or high uric acid levels. If you have diarrhoea that lasts for more than a week, your doctor may need to give you a fluid and salt replacement.

The Consumer Medicine Information can be found on the Janssen website (available from https://www.janssen.com/newzealand/sites/www_janssen_com_newzealand/files/prod_files/live/imbruvica_cmi.pdf) or by contacting Janssen Medical Information on 0800 800 806. Janssen-Cilag (New Zealand) Ltd, PO Box 62185, Sylvia Park, Auckland 1644, New Zealand.
Date of Preparation: 12 April 2022

IMBRUVICA is a fully funded medicine for chronic lymphocytic leukaemia, including small lymphocytic lymphoma - restrictions apply. IMBRUVICA is not funded for patients with mantle cell lymphoma or Waldenström's macroglobulinaemia. A pharmacy charge and normal doctor's fees will apply.

Scan to access
Consumer
Medicine
Information



imbruvica[®]

(ibrutinib)

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