IMBRUVICA® Capsules and Tablets

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using IMBRUVICA?

IMBRUVICA contains the active ingredient ibrutinib. IMBRUVICA is used to treat the following blood cancers in adults: Mantle Cell Lymphoma (MCL); Chronic Lymphocytic Leukaemia (CLL), including Small Lymphocytic Lymphoma (SLL); Waldenström's macroglobulinemia (WM)
For more information, see Section 1. Why am I using IMBRUVICA? in the full CMI.

2. What should I know before I use IMBRUVICA?

Do not use if you have ever had an allergic reaction to IMBRUVICA or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use IMBRUVICA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with IMBRUVICA and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use IMBRUVICA?

- The recommended dose of IMBRUVICA for: MCL is 560 mg once a day and for WM and CLL/SLL is 420 mg once a day. Follow your doctor's instructions on the dose appropriate for you.

More instructions can be found in Section 4. How do I use IMBRUVICA? in the full CMI.

5. What should I know while using IMBRUVICA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using IMBRUVICA • Your heart function will be checked before and during treatment with IMBRUVICA. Your doctor will check your

	blood counts before or during the treatment.
Things you should not do	• Do not change your dose or stop taking IMBRUVICA until your doctor tells you to. • Do not use preparations containing St John's Wort while you are taking IMBRUVICA. • Do not fall pregnant while you are taking IMBRUVICA. • Do not breast feed while you are taking IMBRUVICA.
Driving or using machines	• You may feel tired or dizzy after taking IMBRUVICA, which may affect your ability to drive or use any tools or machinery.
Drinking alcohol	• No information on the effects of drinking alcohol with IMBRUVICA
Looking after your medicine	• Store below 30°C. Keep capsules or tablets in the original container.

	• Do not store it or any medicines in the bathroom or near a sink.

For more information, see Section 5. What should I know while using IMBRUVICA? in the full CMI.

6. Are there any side effects?

The most common side effects include diarrhoea; feeling very tired; nausea; headache; swollen hands, ankles or feet; being short of breath; dizziness; fainting; constipation; infected nose, sinuses or throat (cold); fever; vomiting; decreased appetite; bleeding; bruises; skin rash; muscle and joint pain; muscle spasms; indigestion (dyspepsia).

Call your doctor or healthcare professional if you have signs or symptoms of serious bleeding, if you have any heart problems like chest discomfort, shortness of breath or palpitations or signs of jaundice. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

IMBRUVICA® Capsules and Tablets

Active ingredient(s): *ibrutinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using IMBRUVICA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using IMBRUVICA.**

Where to find information in this leaflet:

1. Why am I using IMBRUVICA?

IMBRUVICA contains the active ingredient ibrutinib. IMBRUVICA is Bruton's tyrosine kinase inhibitor. By blocking this protein, IMBRUVICA may help kill and reduce the number of cancer cells and may also slow the spread of the cancer.

IMBRUVICA is used to treat the following blood cancers in adults: Mantle Cell Lymphoma (MCL); Chronic Lymphocytic Leukaemia (CLL), including Small Lymphocytic Lymphoma (SLL); Waldenström's macroglobulinemia (WM).

2. What should I know before I use IMBRUVICA?

Warnings

Do not use IMBRUVICA if:

- you are allergic to ibrutinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you use preparations containing St John's Wort
- you are pregnant, think you may be pregnant or are planning to have a baby
- you are breast feeding

Check with your doctor if you:

- had unusual bruising or bleeding or are on any medicines or supplements that increase your risk of bleeding
- have had a history of high blood pressure, irregular heartbeat (atrial fibrillation, ventricular tachyarrhythmia) or severe heart failure, or if you feel any of the following: lightheadedness, dizziness,

shortness of breath, chest discomfort, swollen legs, or you faint

- if you have liver or kidney problems
- if you have or have had Hepatitis B infection
- if you have recently had any surgery, especially if this might affect how you absorb food or medicines from your stomach or gut
- if you are planning to have any surgery - your doctor may ask you to stop taking IMBRUVICA for a short time.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not father a child while taking IMBRUVICA and for 3 months after stopping treatment.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

IMBRUVICA may make you bleed more easily. Tell your doctor if you take other medicines that increases your risk of bleeding. These include the following medicines:

- **warfarin, heparin or other medicines to prevent blood clots.**
- **aspirin and non-steroidal anti-inflammatories (NSAIDS) such as ibuprofen or naproxen**
- **fish oil and supplements containing vitamin E**

Some medicines may interfere with IMBRUVICA and affect how it works.

- medicines called antibiotics to treat bacterial infections - clarithromycin, telithromycin, ciprofloxacin, erythromycin, rifampin or azithromycin
- medicines for fungal infections - ketoconazole, posaconazole, itraconazole, fluconazole or voriconazole
- medicines for HIV infection - ritonavir, cobicistat, indinavir, nelfinavir, saquinavir, amprenavir, atazanavir, darunavir/ritonavir or fosamprenavir
- aprepitant - medicine to prevent nausea and vomiting associated with chemotherapy
- nefazodone - medicine for depression
- medicines called kinase inhibitors for treatment of other cancers - crizotinib, imatinib
- medicines called calcium channel blockers for high blood pressure or chest pain - diltiazem, verapamil
- medicines used to treat or prevent irregular heartbeat - amiodarone, dronedarone

- fluvoxamine - medicine used to treat obsessive compulsive disorder
- medicines to prevent seizures or to treat epilepsy or medicines to treat a painful condition of the face called trigeminal neuralgia - carbamazepine, phenytoin
- medicines called statins to treat high cholesterol - rosuvastatin
- St. John's Wort - herbal medicine used for depression

If you are taking digoxin, a medicine used for heart problems, or methotrexate, a medicine used to treat other cancers and to reduce the activity of the immune system (e.g., for rheumatoid arthritis or psoriasis), it should be taken at least 6 hours before or after IMBRUVICA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect IMBRUVICA.

4. How do I use IMBRUVICA?

How much to take / use

- The recommended dose of IMBRUVICA for:
- MCL is 560 mg once a day.
- WM and CLL/SLL is 420 mg once a day.
- Follow your doctor's instructions on the dose appropriate for you.

When to take / use IMBRUVICA

- Do not take IMBRUVICA with grapefruit or Seville oranges - this includes eating them, drinking the juice, or taking supplements that might contain them. This is because they can increase the amount of IMBRUVICA in your blood.
- Swallow IMBRUVICA capsules whole with a glass of water. Do not open, break, or chew them.
- Swallow IMBRUVICA tablets whole with a glass of water. Do not break or chew them.
- Try to take IMBRUVICA at the same time each day.
- Follow the instructions provided and use IMBRUVICA until your doctor tells you to stop. Do not change your dose or stop taking IMBRUVICA until your doctor tells you to.

If you forget to use IMBRUVICA

IMBRUVICA should be used regularly at the same time each day. If you miss your dose at the usual time, if it is more than 12 hours until your next dose, take the missed dose as soon as possible. Then continue taking IMBRUVICA at the usual scheduled time..

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much IMBRUVICA

If you think that you have used too much IMBRUVICA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 or in New Zealand 0800 POISON or 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using IMBRUVICA?

Things you should do

Be sure to keep all your doctor's appointments so your progress can be checked.

Call your doctor straight away 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.

Remind any doctor, dentist or pharmacist you visit that you are using IMBRUVICA.

Things you should not do

Do not take IMBRUVICA:

- if the packaging is torn or shows signs of tampering.
- if the expiry date (month and year) printed on the pack has passed. If you take IMBRUVICA after the expiry date it may not work.

Effects on the heart

- Treatment with IMBRUVICA may affect the heart, especially if you already have heart diseases such as rhythm problems, heart failure, high blood pressure or have diabetes. The effects may be severe and could cause death, including sometimes sudden death. Your heart function will be checked before and during treatment with IMBRUVICA. Tell your doctor immediately if you feel breathless, have difficulty breathing when lying down, swelling of the feet, ankles or legs and weakness/tiredness during treatment with IMBRUVICA – these may be signs of heart failure.

Tests and check-ups before and during treatment

- Laboratory tests may show that your blood count contains more white blood cells (called "lymphocytes"), in the first few weeks of treatment. This is expected and may last for a few months. This does not necessarily mean that your blood cancer is getting worse. Your doctor will check your blood counts before or during the treatment and in rare

cases they may need to give you another medicine. Talk to your doctor about what your test results mean.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how IMBRUVICA affects you.

IMBRUVICA may cause dizziness in some people which may affect your ability to drive or use any tools or machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

We have no information on how alcohol affects IMBRUVICA.

Looking after your medicine

- Store below 30°C. Keep capsules or tablets in the original container.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: diarrhoea; nausea, constipation; vomiting; sore stomach; indigestion (dyspepsia); sore or inflamed mouth; decreased appetite **Infections:**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
infected nose; sinuses or throat; fever; feeling tired; urinary tract infection; chills; body aches; cold or flu symptoms; feel short of breath; yellowing of the skin or eyes (jaundice); confusion **Musculoskeletal:** muscle and joint pain; muscle spasms **Skin:** rash, bruising; swollen hands or feet; bleeding **Nervous system:** dizziness, fainting; headache; blurred vision **Metabolism:** low blood sodium; high levels of uric acid or creatine in your blood	

Serious side effects

Serious side effects	What to do
Bleeding: Bleeding in the eye or serious internal bleeding, such as bleeding in your stomach, intestine, or brain may occur. Signs or symptoms of serious bleeding include blood in your stools or urine or bleeding that lasts for a long time or that you cannot control. **Interstitial lung disease (ILD):** Inflammation within the lungs that may lead to permanent damage has happened with IMBRUVICA treatment. Contact your doctor if you have difficulty breathing or have a persistent cough. **Haemophagocytic lymphohistiocytosis:**	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
There have been rare reports of excessive activation of white blood cells associated with inflammation, which can be fatal if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, bruising, or skin rash, contact your doctor immediately. **Stroke:** Temporary or permanent decrease of brain or nerve function due to reduced blood flow to the brain (mini-stroke or stroke). **Heart problems:** Irregular heartbeat (atrial fibrillation, ventricular tachyarrhythmia) and high blood pressure have occurred with IMBRUVICA treatment. Tell your doctor or healthcare professional if you have any heart problems like chest discomfort, shortness of	

Serious side effects	What to do
breath or palpitations. Heart failure has also been reported. Tell your doctor immediately if you notice breathlessness, difficulty breathing when lying down, swelling of the feet, ankles or legs and weakness/tiredness during treatment with IMBRUVICA. **Rupture of spleen:** Cases of splenic rupture have been reported after stopping IMBRUVICA treatment. Tell your doctor immediately if you develop left upper belly (abdominal) pain, pain below the rib cage or at the tip of your left shoulder. **Changes in blood cell counts:** IMBRUVICA may cause you to have a low number of red blood cells (anaemia), a low number of neutrophils a	

Serious side effects	What to do
type of white blood cell (neutropenia) or a low number of platelets a type cell that help blood to clot (thrombocytopenia). You may experience an increase in the number of white blood cells, specifically lymphocytes in your blood. In rare cases, this increase may be severe, causing cells to clump together. Your doctor or healthcare professional should check your blood counts regularly. **Liver problems:** Very rarely patients may experience changes in their liver function. Your doctor will monitor your liver function by periodic blood tests. If you notice signs of jaundice such as yellowing of the whites of the eyes please call your doctor immediately. **Other cancers:**	

Serious side effects	What to do
New cancers have occurred in people taking IMBRUVICA, including skin cancer and other cancers. **Acute kidney injury:** Is where your kidneys suddenly stop working properly.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What IMBRUVICA capsules contain

Active ingredient **(main ingredient)**	Ibrutinib Each hard capsule contains 140 mg of ibrutinib.
Other ingredients **(inactive ingredients)**	croscarmellose sodium microcrystalline cellulose sodium lauryl sulphate magnesium stearate gelatin titanium dioxide (E171) black ink
Potential allergens	None

What IMBRUVICA tablets contain

Active ingredient **(main ingredient)**	Ibrutinib

	Each tablet contains 140 mg, 280 mg, 420 mg or 560 mg of ibrutinib
Other ingredients **(inactive ingredients)**	colloidal anhydrous silica croscarmellose sodium lactose monohydrate magnesium stearate microcrystalline cellulose povidone sodium lauryl sulfate The film-coating contains: iron oxide black (140 mg, 280 mg and 420 mg tablets) polyvinyl alcohol macrogol iron oxide red (280 mg and 560 mg tablets) talc titanium dioxide iron oxide yellow (140 mg, 420 mg and 560 mg tablets)

Potential allergens	Contains lactose

Do not take this medicine if you are allergic to any of these ingredients.

What IMBRUVICA looks like

140 mg capsule: AUST R 228499

140 mg tablet: AUST R 319356

280 mg tablet: AUST R 319357

420 mg tablet: AUST R 319360

560 mg tablet: AUST R 319380

Capsules

The hard capsules are white opaque, with "ibr 140 mg" printed in black ink.

IMBRUVICA capsules are supplied in bottles containing 90 or 120 capsules. Not all pack sizes may be marketed.

Tablets

140 mg tablets are yellow-green to green, round, debossed with “ibr” on one side and “140” on the other.

280 mg tablets are purple, oblong-shaped, debossed with “ibr” on one side and “280” on the other.

420 mg tablets are yellow-green to green, oblong-shaped debossed with “ibr” on one side and “420” on the other.

560 mg tablets are yellow to orange, oblong-shaped, debossed with “ibr” on one side and “560” on the other.

IMBRUVICA 140 mg, 280 mg, 420 mg and 560 mg tablets are supplied in cartons containing 30 tablets (3 cardboard wallets containing 10 film-coated tablets each).

Not all pack sizes may be marketed

Who distributes IMBRUVICA

Janssen-Cilag Pty Ltd

1-5 Khartoum Rd

Macquarie Park

NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

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Co-developed with Pharmacyclics.