IMBRUVICA® Capsules and Tablets

ibrutinib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IMBRUVICA capsules and tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given IMBRUVICA against the benefits this medicine is expected to have for you.

If you have any questions or concerns about taking IMBRUVICA ask your doctor or healthcare professional.

Keep this leaflet while you are taking IMBRUVICA.

You may need to read it again.

What IMBRUVICA is used for

IMBRUVICA is an anticancer medicine that contains the active substance ibrutinib.

IMBRUVICA is used to treat the following blood cancers in adults:

- Mantle Cell Lymphoma (MCL), a type of cancer affecting the lymph nodes;
- Chronic Lymphocytic Leukaemia (CLL), including Small Lymphocytic Lymphoma (SLL), a type of cancer affecting a type of white blood cell called lymphocytes that also involve the lymph nodes.
- Waldenström's macroglobulinemia (WM), a very rare cancer affecting the lymphocytes

IMBRUVICA works by blocking a protein in the body that helps cancer cells live and grow. This protein is called Bruton's tyrosine kinase. By blocking this protein, IMBRUVICA may help kill and reduce the number of cancer cells and may also slow the spread of the cancer.

Ask your doctor or healthcare professional if you have any questions about why IMBRUVICA has been prescribed for you.

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

Before you take IMBRUVICA

When you must not use it:

Do not take IMBRUVICA:

- if you are allergic (hypersensitive) to ibrutinib, or other ingredients of IMBRUVICA. See Product Description at the end of this leaflet for a list of ingredients.

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.

Do not use preparations containing St John's Wort while you are taking IMBRUVICA.

Do not fall pregnant while you are taking IMBRUVICA.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or healthcare professional for advice before taking IMBRUVICA.

- IMBRUVICA should not be used during pregnancy.
- There is no information about the safety of IMBRUVICA in pregnant women.
- Women of childbearing age must use an effective method of birth control during and up to three months after receiving IMBRUVICA to avoid becoming pregnant while being treated with IMBRUVICA. The time period following treatment with IMBRUVICA where it is safe to become pregnant is not known.
- Tell your doctor immediately if you become pregnant.

Breastfeeding during IMBRUVICA treatment is not recommended.

- It is not known whether IMBRUVICA passes into breast milk.

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

- Use condoms and do not donate sperm during treatment and for 3 months after your treatment has finished. If you plan to father a child, talk to your doctor or healthcare professional before taking IMBRUVICA.

IMBRUVICA should not be used by anyone under 18 years of age because it has not been studied in this age group.

Before you start to use it:

Tell your doctor if you have or have had any medical conditions, especially the following:

- **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 heart beat (atrial fibrillation, ventricular tachyarrhythmia) or severe heart failure, which makes you short of breath and may lead to swollen legs**
- **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.**
- **you have any other medical condition**

Taking other medicines:

IMBRUVICA may make you bleed more easily. Tell your doctor if you take other medicine that increase 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

The effect of IMBRUVICA or other medicines may be influenced when taking IMBRUVICA with some other medicines. **Tell your doctor if you take any of the following medicines:**

- medicines called antibiotics to treat bacterial infections - clarithromycin, telithromycin, ciprofloxacin, erythromycin or rifampin
- 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
- medicine to prevent nausea and vomiting associated with chemotherapy - aprepitant
- medicine for depression - nefazodone
- 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
- medicine used to treat or prevent irregular heartbeat - amiodarone, dronedarone
- 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.

IMBRUVICA might interact with other medicines. This may result in greater or lesser effects or even side effects from these medicines.

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 reduce the dose.

Taking IMBRUVICA

Always take IMBRUVICA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

How much IMBRUVICA to take:

The recommended dose of IMBRUVICA for:

- MCL is 560 mg once a day.
- WM and CLL/SLL is 420 mg once a day.

Your doctor may combine IMBRUVICA with other medicines.

Instructions:

- **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.**

How long to take

Take IMBRUVICA exactly as prescribed by your doctor or healthcare professional. Do not change your dose or stop taking IMBRUVICA until your doctor tells you to.

What do I do if I forget to take IMBRUVICA?

- **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 less than 12 hours until your next dose, skip the missed dose. Then take the next dose of IMBRUVICA at the usual scheduled time.**
- **Do not take extra capsules to make up the missed dose.**

If you are not sure what to do, contact your doctor or pharmacist.

What do I do if I take too much? (overdose):

Immediately telephone your doctor, or the Poisons Information Centre or go to accident and emergency at you nearest hospital if you think you or anyone else may have taken too much IMBRUVICA. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The Poisons Information Centre telephone numbers are:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

While you are taking IMBRUVICA

Things you must do:

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

Your doctor may order certain tests, including blood tests, from time to time to make sure the medicine is working and to prevent unwanted side effects.

Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.

Tell any other doctors and pharmacists who are treating you that you are taking IMBRUVICA.

If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking IMBRUVICA. If you have any questions on the use of this product, ask your doctor or pharmacist.

Things to be careful of

Be careful when driving or operating machinery until you know how IMBRUVICA affects you.

Imbruvica may make you feel tired or dizzy. Do not drive or operate any tools or machinery if you feel dizzy.

Side Effects

Like all medicines, IMBRUVICA can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

- Bleeding: You may experience bruising or nosebleeds during treatment with IMBRUVICA. Rarely, bleeding in the eye or 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.
- Leukostasis: 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 will monitor your blood counts.
- Infections: You may experience viral, bacterial, or fungal infections during treatment with IMBRUVICA. Contact your doctor if you have fever, chills, body aches, cold or flu symptoms, feel tired or feel short of breath, yellowing of the skin or eyes (jaundice), confusion or have pain when urinating - these could be signs of an infection.
- Progressive Multifocal Leukoencephalopathy (PML) is a very rare but serious brain infection which can be fatal. Tell your doctor or healthcare professional immediately if you experience memory loss, trouble thinking, difficulty walking or sight loss. These may be signs of PML.
- Decrease in blood cell counts: Use of IMBRUVICA may cause

you to have a low number of red blood cells (anaemia), a low number of neutrophils a type of white blood cell (neutropenia) or a low number of platelets a type cell that help blood to clot (thrombocytopenia). Your doctor or healthcare professional should check your blood counts regularly.

- 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.
- Irregular heart beat (atrial fibrillation, ventricular tachyarrhythmia) and high blood pressure has occurred with IMBRUVICA treatment. Tell your doctor or healthcare professional if you have any heart problems like chest discomfort, shortness of breath or palpitations.
- Stroke: Temporary or permanent decrease of brain or nerve function due to reduced blood flow to the brain (mini-stroke or stroke). Tell your doctor or healthcare professional immediately if you have numbness or weakness in the limbs (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sight loss, difficulty walking, loss of balance or lack of coordination or sudden severe headache. These may be signs of a stroke.
- Other cancers: New cancers have occurred in people taking IMBRUVICA, including skin cancer and other cancers.
- Liver problems: Very rarely patients may experience changes in their liver function which could be life threatening. 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.

The most common side effects seen include: diarrhoea; low number of a type of white blood cell (neutrophils), bleeding (eg bruising); low number of 'platelets' (cells that help blood to clot); 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); cough; trouble sleeping; anxiety; discharge with itching of the eyes and crusty eyelids; constipation; fever; vomiting; decreased appetite; bruises; skin rash; red or purple, flat, pinhead spots under the skin; urinary tract infection; high blood pressure; muscle spasm; muscle and joint pain; blurred vision; sore stomach and low blood sodium or potassium or high uric acid levels (shown in blood tests), which may cause gout.

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Product Description

Storage

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

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

Heat and dampness can destroy some medicines.

Keep this medicine out of the sight and reach of children.

A locked cupboard at least one-and - a-half metres above the ground is a good place to store medicines.

Do not use this medicine after the expiry date which is stated on the package after EXP.

What it looks like:

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 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.

Not all pack sizes may be marketed.

Ingredients

Capsules

Active ingredient:

- ibrutinib

Each hard capsule contains 140 mg of ibrutinib.

Other ingredients:

- croscarmellose sodium
- microcrystalline cellulose
- sodium lauryl sulphate
- magnesium stearate
- gelatin
- titanium dioxide (E171)
- iron oxide black (E172)
- shellac (E904)

Tablets

Active ingredient:

- ibrutinib

Each tablet contains 140 mg, 280 mg, 420 mg or 560 mg of ibrutinib.

Other ingredients:

- colloidal anhydrous silica
- croscarmellose sodium
- lactose monohydrate
- magnesium stearate
- microcrystalline cellulose
- povidone
- sodium lauryl sulfate
- film-coating (Opadry® II 85F210036 green for 140 mg and 420 mg tablets, Opadry® II 85F200011 purple for 280 mg tablets, Opadry® II 85F32547 yellow for 560 mg tablets)

Sponsor

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