IMBRUVICA® Capsules

ibrutinib

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IMBRUVICA capsules. 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 concerns about being given 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 one month after receiving IMBRUVICA to avoid becoming pregnant while being treated with IMBRUVICA. If using hormonal contraceptives such as birth control pills or devices, a barrier method of contraception (e.g. condoms) must also be used. 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.

Do not breast feed while you are taking IMBRUVICA.

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) 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 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:

Tell your doctor if you take any of the following medicines:

- warfarin, heparin or other medicines to prevent blood clots.
- aspirin and non-steroidal anti-inflammatories (NSAIDS) such as ibuprofen or naproxen
- 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
- medicines to prevent seizures or to treat epilepsy or medicines to treat a painful condition of the face called trigeminal neuralgia - carbamazepine, phenytoin
- 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 four 140 mg capsules once a day.
- WM and CLL is three 140 mg capsules once a day.

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.**
- **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):

If you think you or anybody else has taken too much IMBRUVICA, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

- 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.

Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.
Ask your doctor or pharmacist if you have any questions.

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 further questions on the use of this product, ask your doctor.

Things to be careful of

Driving and using machines
You may feel tired or dizzy after taking IMBRUVICA, which may affect your ability to drive or use any tools or machinery.

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, 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 - these could be signs of an infection.
- 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.
- Heart problems: 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.
- 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. 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; 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; low number of a neutrophils (neutropenia); low number of platelets (thrombocytopenia) and low number of red blood cells (anaemia); bruises; skin rash; muscle and joint pain and low blood sodium levels.

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.

If you get have any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this document.

Product Description

Storage

Store below 30°C. Keep capsules 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:

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

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

Ingredients

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)

Sponsor

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

Registration number

140 mg capsule: AUST R 228499

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