ข้อมูลยาภาษาอังกฤษสำหรับผู้ป่วย

PATIENT INFORMATION

IMBRUVICA® (im-BRU-vih-kuh) (ibrutinib) 140 mg capsules	**IMBRUVICA® (im-BRU-vih-kuh)** (ibrutinib) 140mg, 280mg, 420mg and 560mg tablets

What is IMBRUVICA?

IMBRUVICA is a prescription medicine used to treat adults with:

- Mantle cell lymphoma (MCL) who have received at least one prior treatment
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL)
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)
- Marginal zone lymphoma (MZL) who require a medicine by mouth or injection (systemic therapy) and have received a certain type of prior treatment
- Chronic graft versus host disease (cGVHD) after failure of 1 or more lines of systemic therapy

It is not known if IMBRUVICA is safe and effective in children.

Before taking IMBRUVICA, tell your healthcare provider about all of your medical conditions, including if you:

- have had recent surgery or plan to have surgery. Your healthcare provider may stop IMBRUVICA for any planned medical, surgical, or dental procedure.
- have bleeding problems
- have or had heart rhythm problems, smoke, or have a medical condition that increases your risk of heart disease, such as high blood pressure, high cholesterol, or diabetes
- have an infection
- have liver problems
- are pregnant or plan to become pregnant. IMBRUVICA can harm your unborn baby. If you are able to become pregnant, your healthcare provider will do a pregnancy test before starting treatment with IMBRUVICA. Tell your healthcare provider if you are pregnant or think you may be pregnant during treatment with IMBRUVICA.
  - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with IMBRUVICA and for 1 month after the last dose.
  - **Males** with female partners who are able to become pregnant should use effective birth control, such as condoms, during treatment with IMBRUVICA and for 1 month after the last dose.
- are breastfeeding or plan to breastfeed. Do not breastfeed during treatment with IMBRUVICA and for 1 week after the last dose. **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking IMBRUVICA with certain other medicines may affect how IMBRUVICA works and can cause side effects.

How should I take IMBRUVICA?

- Take IMBRUVICA exactly as your healthcare provider tells you to take it.
- Take IMBRUVICA 1 time a day.
- Swallow IMBRUVICA capsules or tablets whole with a glass of water.
- Do not open, break, or chew IMBRUVICA capsules.
- Do not cut, crush, or chew IMBRUVICA tablets.
- Take IMBRUVICA at about the same time each day.
- If you miss a dose of IMBRUVICA take it as soon as you remember on the same day. Take your next dose of IMBRUVICA at your regular time on the next day. Do not take extra doses of IMBRUVICA to make up for a missed dose.

- If you take too much IMBRUVICA call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking IMBRUVICA?

You should not drink grapefruit juice, eat grapefruit, or eat Seville oranges (often used in marmalades) during treatment with IMBRUVICA. These products may increase the amount of IMBRUVICA in your blood.

What are the possible side effects of IMBRUVICA?

IMBRUVICA may cause serious side effects, including:

- **Bleeding problems (hemorrhage) are common** during treatment with IMBRUVICA, and can also be serious and may lead to death. Your risk of bleeding may increase if you are also taking a blood thinner medicine. Tell your healthcare provider if you have any signs of bleeding, including:
  - blood in your stools or black stools (looks like tar)
  - pink or brown urine
  - unexpected bleeding, or bleeding that is severe or that you cannot control
  - vomit blood or vomit looks like coffee grounds
  - cough up blood or blood clots
  - increased bruising
  - dizziness
  - weakness
  - confusion
  - change in your speech
  - headache that lasts a long time or severe headache
- **Infections** can happen during treatment with IMBRUVICA. These infections can be serious and may lead to death. Tell your healthcare provider right away if you have fever, chills, weakness, confusion, or other signs or symptoms of an infection during treatment with IMBRUVICA.
- **Heart problems.** Serious heart rhythm problems (ventricular arrhythmias, atrial fibrillation and atrial flutter), heart failure and death have happened in people treated with IMBRUVICA, especially in people who have an infection, an increased risk for heart disease, or have had heart rhythm problems in the past. Your heart function will be checked before and during treatment with IMBRUVICA. Tell your healthcare provider if you get any symptoms of heart problems, such as feeling as if your heart is beating fast and irregular, lightheadedness, dizziness, shortness of breath, swelling of the feet, ankles or legs, chest discomfort, or you faint. If you develop any of these symptoms, your healthcare provider may do tests to check your heart and may change your IMBRUVICA dose.
- **High blood pressure (hypertension).** New or worsening high blood pressure has happened in people treated with IMBRUVICA. Your healthcare provider may start you on blood pressure medicine or change current medicines to treat your blood pressure.
- **Decrease in blood cell counts**. Decreased blood counts (white blood cells, platelets, and red blood cells) are common with IMBRUVICA, but can also be severe. Your healthcare provider should do monthly blood tests to check your blood counts.
- **Second primary cancers.** New cancers have happened during treatment with IMBRUVICA, including cancers of the skin or other organs.
- **Tumor lysis syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your healthcare provider may do blood tests to check you for TLS.

The most common side effects of IMBRUVICA in adults with B-cell malignancies (MCL, CLL/SLL, WM and MZL) include:

- diarrhea
- tiredness
- muscle and bone pain
- rash
- bruising

The most common side effects of IMBRUVICA in adults with cGVHD include:

- tiredness
- bruising
- diarrhea
- mouth sores (stomatitis)
- muscle spasms
- nausea
- pneumonia

Diarrhea is a common side effect in people who take IMBRUVICA. Drink plenty of fluids during treatment with IMBRUVICA to help reduce your risk of losing too much fluid (dehydration) due to diarrhea. Tell your healthcare provider if you have diarrhea that does not go away.

These are not all the possible side effects of IMBRUVICA.

Call your doctor for medical advice about side effects. You may report side effects to FDA.

How should I store IMBRUVICA?

- Do not store IMBRUVICA above 30°C.
- Keep IMBRUVICA capsules in the original container with the lid tightly closed.
- See expiry date on the outer pack.
- Keep IMBRUVICA tablets in the original carton.

Keep IMBRUVICA and all medicines out of the reach of children.

General information about the safe and effective use of IMBRUVICA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use IMBRUVICA for a condition for which it was not prescribed. Do not give IMBRUVICA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about IMBRUVICA that is written for health professionals.

What are the ingredients in IMBRUVICA?

Active ingredient: ibrutinib

Inactive ingredients:

IMBRUVICA capsules: croscarmellose sodium, magnesium stearate, microcrystalline cellulose and sodium lauryl sulfate. The 140 mg capsule shell contains gelatin, titanium dioxide, and black ink.

IMBRUVICA tablets: colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, and sodium lauryl sulfate. The film coating for each tablet contains ferrosoferric oxide (140 mg, 280 mg, and 420 mg tablets), polyvinyl alcohol, polyethylene glycol, red iron oxide (280 mg and 560 mg tablets), talc, titanium dioxide, and yellow iron oxide (140 mg, 420 mg, and 560 mg tablets).

Nature and contents of container

Capsules: HDPE bottles with a child resistant polypropylene closure. Each carton contains one bottle of either 90 or 120 hard capsules.

Tablets: Polyvinyl chloride (PVC) laminated with polychlorotrifluoroethylene (PCTFE)/aluminum push-through blisters. Each carton contains 30 film-coated tablets in blister wallets.

Not all pack sizes may be marketed.

Manufactured by	**Dosage Forms**	**Market Authorization Number**	**Date of Authorization**
Catalent CTS, LLC. Kansas City, MO 64137, USA	Capsules 140 mg	1C 15164/63 (N)	02 November 2017 Renewal date: 9 September 2020 SMP Release date: 27 July 2022
Cilag AG CH-8200 Schaffhausen, Switzerland	Capsules 140 mg	1C 73/60 (N)	02 November 2017 SMP Release date: 27 July 2022
	Film-coated tablets 140mg	1C 15027/64 (NC)	25 March 2021
	Film-coated tablets 280mg	1C 15028/64 (NC)	25 March 2021
	Film-coated tablets 420mg	1C 15029/64 (NC)	25 March 2021
	Film-coated tablets 560mg	1C 15030/64 (NC)	25 March 2021

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To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Please see full prescribing information at https://ndi.fda.moph.go.th/

Warning according to the announcement from Ministry of Public Health
This medicinal product may cause serious harm. It must be used only under physician's supervision.