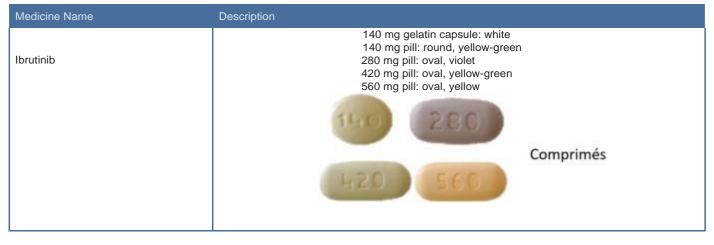


Patient Information Leaflet Ibrutinib – IMBRUVICA®

What is IMBRUVICA®



How should you take your medicine?

Your doctor has determined your medicine dosage.

At a set time, with or without meals.

If you forgot to take a dose or in case of vomiting, do not take an additional dose but wait for the time to take the next dose.

Dosage – therapy regimen



How to get the medicine supply?

This medicine is available in local pharmacies.

Getting this medicine might take time. Be careful and order the medicine in advance. Store this product in its original packaging, away from sources of heat and moisture.

What else do you need to know?

Precautions and monitoring

Laboratory tests are necessary while taking your medication (blood test to monitor blood counts), as well as clinical condition monitoring (ECG).

Using contraceptives

This drug may harm an unborn baby. During the entire treatment, you and your partner need to use effective contraception methods (condoms, oral contraceptive combined with another method).

Interactions with other medications and/or food

The occurrence of interactions between IMBRUVICA® and your other treatments may have harmful consequences (reduced drug efficacy and tolerance). It is important to tell your pharmacist and doctor about all medications and/or other substances (foods, plants, probiotics, essential oils, nutritional supplements, etc.) that you are taking.

Example: While taking IMBRUVICA®, it is necessary to avoid using Saint John's wort and grapefruit.

What are possible side effects?

Only the most common side effects are listed below. There might be some other side effects. For additional information, refer to your medicine leaflet or seek advice from your doctor or pharmacist.

SIDE EFFECTS



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ed on June 8, 2021 Most common ones	Digestive problems: diarrhea, nausea, vomiting, constipation, inflammations inside the mouth (ulcers),
	of appetite
	General disorders: fatigue, legs and/or arms swelling
	Infections: fever, respiratory infections (pharyngitis, laryngitis, sinusitis, rhinitis, pneumonia, etc.)
	Muscular problems: joint pain, muscular spasms, pain in muscles Neurological disorders: headaches, dizziness
	Vascular disorders: nontypical bleedings, spots on the skin, hematomas, hypertension Skin problems: skin rash
	Abnormal lab results: low multinuclear neutrophil count (neutropenia) and/or low platelet count
	(thrombocytopenia), low hemoglobin level (anemia) Cardiac problems
WHEN TO ALERT THE MEDIO	L CAL TEAM?
	Digestive problems
	> Significant and/or rapid weight loss
Tell medical personnel if the following conditions are	 > Very frequent diarrhea, bowel movement over 4 times a day > Mouth pain or ulcers that prevent normal eating
present and in the absence	> Severe abdominal pain
of specific medical advice	 Inability to drink for 24 hours and/or eat for about 48 hours Bowel movements fewer than 3 times a week
	Worsening of skin problem
	> Pain and inflammation in hands and feet
	Symptoms suggestive of infection > Temperature > 38.5 °C
	> Cough, throat pain, pain on urination, diarrhea with fever
	Respiratory problems
	 Increasing constant cough or problems breathing Symptoms suggestive of bleeding
	> Blood in stool or in vomit
	 > Hematomas (bruises), nose bleedings Symptoms suggestive of cerebral edema
	Headaches, confusion, convulsions, or vision problems
	Pain that prevents you from doing your normal activities > Headaches
	> Joint pian
HOW TO PREVENT SIDE EFF	ECTS?
Weight	Regularly check your weight in case of digestive problems or swelling in the arms or legs.
Skin care	On hands and feet: Apply moisturizing cream or milk and/or healing cream on hands and feet (withou
	rubbing hard).
	Avoid exposing hands and feet to heat (hot water). Avoid activities that cause rubbing or injury. Avoid wearing overly tight clothing, socks, or shoes
	Body: Opt for soft soap and moisturizer, pat skin dry.
	Avoid using any irritating products. For sun protection, use broad spectrum sunscreen and avoid sun exposure.
Oral hygiene	Use a soft toothbrush; use oral rinses containing baking soda.
Infection	 Avoid oral rinses that contain menthol or alcohol. Avoid visiting high risk areas (crowds, contact with sick people,). A flu and pneumococcal infection vaca
Bleedings / hemmorhages	might be recommended for you: it will protect you. Avoid taking anti-inflammatory drugs (ibuprofen, aspirin)
Discoungs / neminomages	Notify your doctor:
	 > if you take <i>blood thinners or thrombocytic antiaggregants</i>: careful monitoring is needed > about <i>surgical or dental intervention</i>
Fatigue	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walkin
	work in the garden, swimming, biking, sports Alternate periods of activity and rest.
Swelling	Avoid wearing tight clothing, socks, and shoes. Put your feet in an elevated position.
Constipation / joint pain	To stimulate intestinal transit, engage in adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports
Handling an anticancer	Avoid capsule contact with skin. Wear gloves and wash your hands after handling the medicine.
HOW TO ADAPT YOUR DIET	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas.
Diarmea	Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol. Drink more water.
Constipation	Opt for a high fiber diet. Drink more water.
Weight loss	Opt for a higher calorie diet and "pleasure diet".
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes.
	Limit consumption of fatty, fried, and spicy foods.
	Avoid sour, sticky, or very salty foods.
Inflammation inside mouth (ulcers)	



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