

### **Patient Information Leaflet**

# Zanubrutinib – BRUKINSA®

## What is BRUKINSA®

Medicine Name	Description					
	80 mg white capsule, "ZANU 80" printed on it.					
Zanubrutinib	ZANU 80					

# How should you take your medicine?

Swallow whole with a glass of water. Do not open or chew the capsules.

At a set time, with or without meals.

If forgotten, the dose can be taken within 3 hours. After 3 hours, wait for the next dose.

In case of vomiting, do not take an additional dose but wait for the time to take the next dose.

# Dosage - therapy regimen

Once or twice a day, at a set time, with or without meals		\$\frac{\sqrt{1}}{\sqrt{2}}			101			iOI	
With no gaps	D1	D2	D3	D4	<b>D</b> 5	D6	<b>D</b> 7	•••	D28

### 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). Lymphocytes may increase during the first weeks of treatment (on your blood tests): this is normal and is not an adverse effect.

#### 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 BRUKINSA® 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 BRUKINSA®, 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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Most common ones	Digestive problems: diarrhea, constipation General disorders: fatigue, legs and/or arms swelling Infections: fever, respiratory infections (pharyngitis, laryngitis, sinusitis, rhinitis, pneumonia, etc.) Muscular problems: joint pain, 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 MEDIC	CAL TEAM?
Tell medical personnel if the following conditions are present and in the absence of specific medical advice	Digestive problems  > Significant and/or rapid weight loss  > Very frequent diarrhea, bowel movement over 4 times a day  > Mouth pain or ulcers that prevent normal eating  > Severe abdominal pain  > 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 pain
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 (without 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.
Infection	Avoid visiting high risk areas (crowds, contact with sick people). A flu and pneumococcal infection vaccine might be recommended for you: it will protect you.
Bleedings / hemmorhages	Avoid taking anti-inflammatory drugs (ibuprofen, aspirin) and phytotherapy that might increase the risk of bleeding (flaxseed)  Notify your doctor:  > if you take blood thinners or thrombocytic antiaggregants: careful monitoring is needed > about surgical or dental intervention
Fatigue	Opt for activities contributing to well-being, in particular adjusted and regular physical activities: walking, 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, <b>engage in</b> adjusted and regular physical activities: walking, work in the garden, swimming, biking, sports
Handling an anticancer medication	Avoid capsule contact with skin. Wear gloves and wash your hands after handling the medicine.
HOW TO ADAPT YOUR DIET?	
Diarrhea	Opt for a low fiber diet. It is preferable to consume starchy products, carrots, and bananas.  Avoid using raw fruit and vegetables, dairy products, coffee, or alcohol.  Drink more water.
Constipation	Opt for a high fiber diet. Drink more water.
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes.  Limit consumption of fatty, fried, and spicy foods.
Inflammation inside mouth (ulcers)	Avoid sour, sticky, or very salty foods.
Swellings	Opt for a low salt diet.
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