

Patient Information Leaflet Midostaurine – RYDAPT®

What is Midostaurine

Medicine Name	Description
RYDAPT®	25 mg capsule: orange

How should you take your medicine?

Your doctor has determined your medicine dosage.

In your case, the dosage is as follows:..... mg/day, i.e. 25 mg gelatin capsules twice a day

..... (indicate whether to take continuously or not)

Swallow whole with a glass of water, without opening or diluting the capsules.

At a set time, with 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

Twice a day, at a set time, with meals	S	101	101
With no gaps (monotherapy) or with gaps as per protocol (in combination)			

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, blood glucose, potassium level, and liver function), 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 combined with another method).

Interactions with other medications and/or food

The occurrence of interactions between Midostaurine 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 RYDAPT®, 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.



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SIDE EFFECTS		
Most common ones	Abnormal lab results: low white blood cell count (leucopenia – neutropenia), low platelet count (thrombocytopenia), low hemoglobin level (anemia), hyperglycemia Digestive problems: nausea, vomiting, diarrhea, inflammations inside the mouth (ulcers) Skin problems: rash, dryness, sensitivity to sun Cardiac problems, including hypo- or hypertension, legs and/or arms swelling Respiratory problems Others: nose bleedings, headaches, joint pain	
Some patients require special attention	Patients with diabetes (hyperglycemia)	
WHEN TO ALERT THE MEDIC	AL 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 > Severe abdominal pain > Inability to drink for 24 hours and/or eat for about 48 hours 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 Pain that prevents you from doing your normal activities > Headaches > Joint pain Symptoms suggestive of cardiac problems > Shortness of breath, high palpitation, or chest pain or tightness	
HOW TO PREVENT SIDE EFF		
Weight Infection	Regularly check your weight in case of digestive problems or swellings. 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.	
Skin care	Opt for mild soap and moisturizer, pat skin dry. Avoid using any skin irritating products. For sun protection use broad spectrum sunscreen and avoid sun exposure.	
Blood pressure control	Elevated blood pressure needs to be corrected. Taking arterial pressure regularly is recommended. Pharmacists can help you take your blood pressure. You can also ask to do it by yourself using an automatic blood pressure monitor.	
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.	
Nausea	Opt for split nutrition consisting of several light meals, liquid and cold dishes. Limit consumption of fatty, fried, and spicy foods.	