

For the Patient: Midostaurin Other names: RYDAPT®

- **Midostaurin** (mye"doe staw' rin) is a drug that is used to treat some types of cancer. It is a capsule that you take by mouth.
- Tell your doctor if you have ever had an unusual or **allergic reaction** to midostaurin before taking midostaurin.
- **Blood tests** may be taken regularly during treatment. The dose and timing of your treatment may be changed based on the test results and/or other side effects.
- It is important to take midostaurin exactly as directed by your doctor. Make sure you
 understand the directions.
- Take midostaurin with food.
- Do not chew or crush midostaurin capsules. **Swallow whole**.
- If you miss a dose of midostaurin, skip the missed dose and go back to your usual dosing times.
- If you **vomit** the dose of midostaurin, skip the missed dose and go back to your usual dosing times. Do not take any doses to make up for the missed dose. Call your doctor during office hours for advice as a medication to prevent nausea may be required for future doses.
- Other drugs such as ketoconazole (NIZORAL®) and rifampin (RIFADIN®) may interact with midostaurin. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these
 may interact with midostaurin.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of midostaurin.
- Midostaurin may affect fertility in men and women. If you plan to have children, discuss this with your doctor before being treated with midostaurin.

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- Midostaurin may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with midostaurin and for at least four months after your last dose. Hormonal birth control may not work as well while you are taking midostaurin. Talk to your doctor about which birth control options are best for you. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment.
- **Store** midostaurin capsules out of the reach of children, at room temperature, away from heat and light. Keep in original packaging to protect from moisture.
- **Tell** doctors, dentists, and other health professionals that you are being treated with midostaurin before you receive any treatment from them.

Changes in blood counts

Midostaurin may cause temporary changes in your blood counts. Your doctor will be following these changes carefully by performing blood tests. Adjustment of your treatment may be needed in certain circumstances.

BLOOD COUNTS	MANAGEMENT
Normal white blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	 To help prevent infection: Wash your hands often and always after using the bathroom. Avoid crowds and people who are sick. Call your doctor <i>immediately</i> at the first sign of an infection such as fever (over 100°F or 38°C by an oral thermometer), chills, cough, or burning when you pass urine.
Normal platelets help your blood to clot normally after an injury (e.g., cut). When the platelet count is low, you may be more likely to bruise or bleed.	 To help prevent bleeding problems: Try not to bruise, cut, or burn yourself. Clean your nose by blowing gently. Do not pick your nose. Avoid constipation. Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding. Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart). For minor pain, try acetaminophen (e.g., TYLENOL®).

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

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SIDE EFFECTS	MANAGEMENT		
Nausea and vomiting may occur.	You may be given a prescription for antinausea drug(s) to take. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. • Drink plenty of fluids.		
	Eat and drink often in small amounts.		
	• Try the ideas in <i>Practical Tips to Manage Nausea.</i> *		
Skin rashes commonly occur.	If itching or peeling is very irritating, call your doctor. Otherwise, be sure to mention it at your next visit.		
Diarrhea may sometimes occur.	If diarrhea is a problem:		
	Drink plenty of fluids.		
	Eat and drink often in small amounts.		
	 Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.* 		
Constipation may sometimes occur.	Exercise if you can.		
	Drink plenty of fluids.		
	Try ideas in Food Choices to Manage Constipation.*		
Sore mouth may sometimes occur a few days after treatment. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.	Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste.		
	 Make a mouthwash with ½ teaspoon baking soda or salt in 1 cup warm water and rinse several times a day. 		
	Try the ideas in Food Ideas to Try with a Sore Mouth.*		
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.		
Muscle or joint pain may sometimes	Tell your doctor if the pain interferes with		
occur.	your activity.		
	 If needed, you may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. 		

SIDE EFFECTS	MANAGEMENT	
Sugar control may sometimes be affected in diabetic patients.	Check your blood sugar regularly if you have diabetes.	
Swelling around your eyes or in your hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling in your feet or lower legs is a problem:	
	 Elevate your feet when sitting. Avoid tight clothing. Tell your doctor if the swelling does not go 	
You may sometimes have trouble sleeping.	Talk to your doctor if you continue to have trouble sleeping.	
	 This will return to normal when you stop taking midostaurin. 	
Tiredness and lack of energy commonly occurs.	Do not drive a car or operate machinery if you are feeling tired.	
	 Try the ideas in Fatigue/Tiredness – Patient Handout or Your Bank to Energy Savings: Helping People with Cancer Handle Fatigue.* 	
Hair loss does not occur with midostaurin.		

^{*}Please ask your chemotherapy nurse or pharmacist for a copy.

STOP TAKING MIDOSTAURIN AND SEE YOUR DOCTOR OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an infection such as fever (over 100°F or 38°C by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum); cloudy or foul smelling urine; painful, tender, or swollen red skin wounds or sores.
- Signs of **bleeding problems** such as black, tarry stools; blood in urine; pinpoint red spots on skin; extensive bruising.
- Signs of an **allergic reaction** (rare) soon after a treatment including flushing, chest pain, swelling, or breathing problems.
- Signs of heart or lung problems such as fast or uneven heartbeat, chest pain, chest pressure, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.

SEE YOUR DOCTOR AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- Signs of anemia such as unusual tiredness or weakness.
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower legs.
- Signs of **gout** such as joint pain.
- Increased sore throat or mouth that makes it difficult to swallow comfortably.
- Peeling of large areas of skin or skin that is painful.

CHECK WITH YOUR DOCTOR IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- New cough or a cough that gets worse.
- Headache not controlled with acetaminophen (e.g., TYLENOL®).
- Dizziness.
- Feelings of confusion or forgetfulness.
- · Easy bruising or minor bleeding.
- Weight gain.
- For diabetic patients: uncontrolled blood sugars.

REPORT ADDITIONAL PROBLEMS TO YOUR DOCTOR

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