

## Medication Information Sheet

**midostaurin** (MYE-doe-STAW-rin)

*This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.*

**Other Name:** Rydapt™

**Appearance:** Pale orange capsule

**What is this medication for?**

- For treating adults with a type of blood cancer called acute myeloid leukemia (AML) in combination with chemotherapy treatments

**What should I do before I have this medication?**

Tell your health care team if you have or had significant medical condition(s) such as:

- heart problems
- lung problems
- a recent infection, or
- any allergies.

**How will this medication affect sex, pregnancy and breastfeeding?**

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding
  - ► **Use 2 effective forms of birth control at the same time** while taking this drug. Keep using birth control for at least **4 months** after your last dose unless your health care team told you differently. Talk to your health care team to figure out the best method(s) for you and/or your partner.
- Do not breastfeed while using and for 4 months after stopping midostaurin.
- This medication may affect fertility (ability to get pregnant)

## How is this medication given?

- Midostaurin is not taken every day. Your cancer health care team will tell you which days you should take it. Make sure you understand the instructions.
- This medication is usually taken twice a day by mouth, approximately 12 hours apart.
- Take this medication with food to help prevent nausea and vomiting.
- Swallow capsules whole with a glass of water. Do not open, crush, or chew capsules.
- If you miss a dose, skip it and take your next dose as scheduled. Do not double the dose to make up for a missed dose.
- If you vomit after taking a dose, do not take an extra dose. Take your next dose as scheduled.

## What else do I need to know while on this medication?

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects. Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements), especially if you are taking medication for an infection, epilepsy, a heart problem, or St. John's Wort. Check with your health care team before starting or stopping any of them.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of drug in your blood and increase side effects.
- For mild aches and pain:
  - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
  - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications. If you feel unwell, take your temperature before taking any of these medications. They may hide a fever. **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

## How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.

## What are the side effects of this medication?

The following side effects have been seen in people using midostaurin with other chemotherapy drugs, so some of these effects may be caused by chemotherapy. You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
<b>Very Common (50 or more out of 100 people)</b>	
<p><b>Abnormal liver lab tests</b></p> <ul style="list-style-type: none"> <li>• You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens.</li> <li>• Your doctor may monitor your liver regularly with a blood test.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Unusual bleeding or bruising</b></p> <ul style="list-style-type: none"> <li>• You may have black stools (poo), cough up blood, blood in your pee, purple or red dots on your skin, or bleeding that will not stop.</li> <li>• It may happen in days to weeks after you receive your treatment.</li> <li>• It may be due to low platelets (a type of blood cell).</li> <li>• Take care of your mouth and use a soft toothbrush.</li> <li>• Be careful not to cut or hurt yourself.</li> <li>• Check with your doctor before you have any surgeries and before going to see the dentist.</li> <li>• See the <a href="#">low platelets</a> pamphlet for more information.</li> </ul> <p><b>Fever, chills, infection</b></p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> <li>• <b>38.3°C (100.9°F) or higher at any time OR</b></li> <li>• <b>38.0°C (or 100.4°F) or higher for at least one hour.</b></li> </ul> <p>While you are getting chemotherapy treatments:</p> <ul style="list-style-type: none"> <li>• Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills).</li> <li>• Avoid taking medications that treat a fever before you take your</li> </ul>	Get emergency medical help right away

\*The most updated version and more symptom control information can be found on: <http://www.cancercare.on.ca/druginfo>

Prepared with input from the Cancer Care Ontario-Medication Information Sheets Working Group.

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<b>Very Common (50 or more out of 100 people)</b>	
<p>temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever.</p> <ul style="list-style-type: none"> <li>• Do not eat or drink anything hot or cold right before taking your temperature.</li> <li>• Wash your hands often.</li> <li>• Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist.</li> </ul> <p><b>If you have a fever, talk to your health care team or go to the closest emergency room.</b> See our <a href="#">Neutropenia (Low white blood cell count)</a> pamphlet for more information.</p>	
<p><b>Nausea and vomiting (generally mild)</b></p> <p>May occur in hours to days after your treatment.</p> <p><b>If you have nausea or vomiting:</b></p> <ul style="list-style-type: none"> <li>• Take anti-nausea medication(s) as prescribed to you by your doctor.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (e.g. coffee, tea) and alcohol.</li> <li>• Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting.</li> </ul> <p>Also see <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</p>	Contact your healthcare team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Common (25 to 49 out of 100 people)</b>	
<p><b>Headache; mild joint, muscle pain or cramps</b></p> <ul style="list-style-type: none"> <li>• Take your pain medication as prescribed by your doctor.</li> <li>• You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you.</li> <li>• Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk.</li> <li>• Rest often and try light exercise as it may help.</li> </ul>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
<b>Less Common (10 to 24 out of 100 people)</b>	
<p><b>Mouth sores</b></p> <p>You may have round, painful, white or gray sores inside your mouth. They can occur on the tongue, lips, gums, or inside your cheeks. In more severe cases they may make it hard to swallow, eat or to brush your teeth. They usually last 1 to 2 weeks.</p> <p><b>To help prevent mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Take care of your mouth by gently brushing and flossing regularly.</li> <li>• Rinse your mouth often. Do not use mouthwashes with alcohol.</li> <li>• Instead, try a homemade mouthwash:</li> <li>• Mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water.</li> </ul> <p><b>If you have mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Check with your health care team as soon as you notice mouth or lip sores or if it hurts to swallow.</li> <li>• Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a mouthwash to relieve mouth sores and prevent infection.</li> </ul> <p>See the <a href="#">Mouth Care</a> pamphlet for more information.</p>	<p>Contact your health care team as soon as possible (office hours)</p>
<p><b>Salt imbalances</b></p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>	<p>Get emergency medical help right away</p>
<p><b>High blood sugar</b></p> <ul style="list-style-type: none"> <li>• You may feel thirsty and pee more often.</li> <li>• Your doctor may check your blood sugar level. You may be advised to change your diet or take medication to treat high blood sugar.</li> <li>• Check your blood sugar regularly if you have diabetes.</li> </ul>	<p>Contact your health care team as soon as possible (office hours)</p>
<p><b>Pains or cramps in the belly</b></p> <ul style="list-style-type: none"> <li>• If you have constipation or diarrhea it may be causing the pain in your belly.</li> <li>• If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes.</li> </ul>	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
<b>Less Common (10 to 24 out of 100 people)</b>	
<p><b>Hemorrhoids</b></p> <p>You may have swollen veins (blood vessels) around the anus that cause pain or bleeding during or after bowel movements (poo).</p>	Contact your health care team if no improvement or if severe
<p><b>Increased sweating</b></p> <p><b>To help prevent sweating :</b></p> <ul style="list-style-type: none"> <li>• Avoid triggers such as alcohol, caffeine (tea, coffee, cola), chocolate, hot &amp; spicy food, stress and heat.</li> <li>• Keep cool and dress lightly or in layers that you can remove. Wear clothes made with natural, breathable materials.</li> <li>• Bathe daily.</li> <li>• Drink plenty of liquids unless you are on liquid restriction.</li> <li>• It may improve over time.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Trouble falling asleep</b></p> <ul style="list-style-type: none"> <li>• This may be caused by one of your medications and may improve once your body gets used to the medication or when your treatment ends.</li> <li>• Talk to your doctor if this bothers you.</li> </ul>	Contact your health care team if no improvement or if severe
<p><b>Sore throat</b></p>	Contact your health care team if no improvement or if severe
<p><b>Heart problems</b></p> <p>You may have an irregular heartbeat, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly.</p>	Get emergency medical help right away

**Other rare, but serious side effects are possible.**

**If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:**

- confusion, severe muscle weakness, seizures
- pain, swelling and hardening of a vein
- new breathing problems or coughing up blood
- high blood pressure

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For more links on how to manage your symptoms go to [www.cancercare.on.ca/symptoms](http://www.cancercare.on.ca/symptoms).

*The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.*

*A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.*

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