

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 certain types of blood cancers or blood disorders, such as acute myeloid leukemia (AML) or mastocytosis.

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.

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until **4 months** after your last dose. Talk to your health care team about which birth control options are best for you.
- This medication may make hormonal birth control, such as birth control pills, less effective (not work as well). If you choose to use a hormonal birth control, make sure you also use a barrier or non-hormonal birth control method (such as condoms). Talk to your health care team about the best birth control options for you.
- Do not breastfeed while on this medication and for at least 4 months after your last treatment dose.

How is this medication given?

- Midostaurin is usually taken twice a day, approximately 12 hours apart.
- Some patients may only need to take midostaurin on certain days of a treatment cycle. Talk to your health care team about how and when to take your medication.
- 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 the missed dose 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, take your next dose as scheduled. Do not take an extra dose.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017

To Prevent or Treat Nausea and Vomiting

You may be given medications to help prevent nausea (feeling like throwing up) and vomiting (throwing up) before they start.

- These are called anti-nausea medications and include medications such as ondansetron (Zofran®), granisetron (Kytril®) or others.

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

- **Will this medication interact with other medications or natural health products?**
 - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.

- Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- Check with your health care team before starting or stopping any of them.
- If you take seizure medications (such as phenytoin), your health care team may monitor your blood levels closely and may change your dose.
- **What should I do if I feel unwell, have pain, a headache or a fever?**
 - **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time
 - OR
 - 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- **Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.**
- Ask your health care team for the [Fever](#) pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)**

is a safe choice for most people.

- ◊ **Talk to your health care team before you start taking** Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- ◊ Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO tell your health care team about any serious infections that you have now or have had in the past.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- 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.

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.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- **How to safely touch oral anti-cancer medications**

If you are a patient:

- ◊ Wash your hands before and after touching your oral anti-cancer medication.
- ◊ Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- ◊ Wear nitrile or latex gloves when touching tablets, capsules or liquids.

- ◊ Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
 - ◊ Throw out your gloves after each use. Do not re-use gloves.
 - ◊ Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.
- **What to do if oral anti-cancer medication gets on your skin or in your eyes**

If medication gets on your skin:

- ◊ Wash your skin with a lot of soap and water.
- ◊ If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

- ◊ Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting midostaurin. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on midostaurin.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Low neutrophils (white blood cells) in the blood (neutropenia)</p> <p>(May be severe)</p> <p>When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • If you feel hot or unwell (for example if you have chills or a new cough), you 	<p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you MUST get emergency medical help right away.</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p>must check your temperature to see if you have a fever.</p> <ul style="list-style-type: none"> Do not take medications that treat a fever before you take your temperature (for example, Tylenol® (acetaminophen), or Advil® (ibuprofen)). Do not eat or drink anything hot or cold right before taking your temperature. <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> 38.3°C (100.9°F) or higher at any time OR 38.0°C (100.4°F) or higher for at least one hour. <p>What to do?</p> <p>If your health care team has told you that you have low neutrophils:</p> <ul style="list-style-type: none"> Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. <p>If you have a fever:</p> <p>If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>	
<p>Low platelets in the blood</p> <p>(May be severe)</p> <p>When your platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the Low Platelet Count pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> Watch for signs of bleeding: <ul style="list-style-type: none"> bleeding from your gums unusual or heavy nosebleeds bruising easily or more than normal 	<p>Talk to your health care team if you have any signs of bleeding. If you have bleeding that doesn't stop or is severe (very heavy), you MUST get emergency help right away.</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> ◦ black coloured stools (poo) or blood in your stools (poo) ◦ coughing up red or brown coloured mucus ◦ dizziness, constant headache or changes in your vision ◦ heavy vaginal bleeding ◦ red or pink coloured urine (pee) <p>What to do?</p> <p>If your health care team has told you that you have low platelets:</p> <ul style="list-style-type: none"> • Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication. • Check with your healthcare team before you go to the dentist. • Take care of your mouth and use a soft toothbrush. • Try to prevent cuts and bruises. • Ask your health care team what activities are safe for you. • Your treatment may have to be delayed if you have low platelets. Your health care team may recommend a blood transfusion. <p>If you have signs of bleeding:</p> <ul style="list-style-type: none"> • If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes. <p>If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.</p>	
<p>Nausea and vomiting</p> <p>(Generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Nausea is feeling like you need to throw up. You may also feel light-headed. • You may feel nausea within hours to days after your treatment. 	<p>Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than to treat it once it happens. • If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (like coffee, tea) and avoid alcohol. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea & Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◦ nausea lasts more than 48 hours ◦ vomiting lasts more than 24 hours or if it is severe 	
<p>Rash with red and peeling skin</p> <p>What to look for?</p> <ul style="list-style-type: none"> • A large area of the skin on your body may look red. • Your skin may itch, burn, sting or feel very tender when touched. • You may have scaly skin patches, thickened skin or your skin may peel off. • You may have a higher chance of getting a skin infection. <p>What to do?</p> <ul style="list-style-type: none"> • Keep your skin moist, especially in the skin folds. • Gently apply moisturizer cream or lotion to the inside of your hands and bottom of your feet as needed. Choose a fragrance-free cream that contains lanolin (like Bag Balm®, Udderly Smooth®) or urea 10% (like Uremol 10®). • Do not let your hands and feet get too hot. Wash sweat from your skin. Bathe or shower in lukewarm water and gently pat yourself dry. • Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, 	<p>Talk to your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p>unless your health care team has told you to drink more or less.</p> <p>In rare cases, rash may be severe if:</p> <ul style="list-style-type: none"> • The rash covers more than a third of your skin (for example your whole trunk, or an arm AND a leg) or • The rash causes your skin to blister or peel. <p>If this happens, talk to your health care team or go to the emergency room right away.</p>	
<p>Diarrhea</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it or told you to take it. • Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol. • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. • Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p>	<p>Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day)</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Headache; sore throat; mild joint, muscle pain or cramps</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Mild headache or sore throat • New pain in your muscles or joints, muscle cramps, or feeling achy. <p>What to do?</p> <ul style="list-style-type: none"> • Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. • Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. • Rest often and try light exercise (such as walking) as it may help. <p>Ask your health care team for the Pain pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Mild swelling</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. <p>What to do?</p> <p>To help prevent swelling:</p> <ul style="list-style-type: none"> • Eat a low-salt diet. <p>If you have swelling:</p> <ul style="list-style-type: none"> • Wear loose-fitting clothing. • For swollen legs or feet, keep your feet up when sitting. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. • Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Ask family or friends to help you with things like housework, shopping, and child or pet care. • Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). • Avoid driving or using machinery if you are feeling tired. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Constipation</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Having bowel movements (going poo) less often than normal. • Small hard stools (poo) that look like pellets. • The need to push hard and strain to have any stool (poo) come out. • Stomach ache or cramps. • A bloated belly, feeling of fullness, or discomfort. • Leaking of watery stools (poo). • Lots of gas or burping. • Nausea or vomiting. <p>What to do?</p> <p>To help prevent constipation:</p> <ul style="list-style-type: none"> • Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> • Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. • Be Active. Exercise can help to keep you regular. • If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation:</p> <ul style="list-style-type: none"> • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. <p>Ask your health care team for the Constipation Pamphlet for more information.</p>	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Mouth sores</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks. • In more severe cases they may make it hard to swallow, eat or brush your teeth. • They may last for 3 days or longer. <p>What to do?</p> <p>To help prevent mouth sores:</p> <ul style="list-style-type: none"> • Take care of your mouth by gently brushing and flossing regularly. • Rinse your mouth often with a homemade mouthwash. • To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. • Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. 	<p>Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>If you have mouth sores:</p> <ul style="list-style-type: none"> • Avoid hot, spicy, acidic, hard or crunchy foods. • Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. • Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. <p>Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.</p>	
<p>High blood sugar</p> <p>(May be severe)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may feel thirsty. • You may pee more often than usual. • You may feel tired or sleepy. <p>What to do?</p> <ul style="list-style-type: none"> • Your health care team may do a blood test to check your blood sugar level. • You may be told to change your diet or given medication to lower your blood sugar. • If you have diabetes, check your blood sugar regularly. Your health care team may ask you to check it more often than usual. 	Talk to your health care team as soon as possible
<p>Changes in heart rhythm</p> <p>This is usually mild with no symptoms. Your health care team may monitor your heart rate for you.</p> <p>What to look for?</p> <p>In severe but rare cases, you may have:</p> <ul style="list-style-type: none"> • an irregular heartbeat, • shortness of breath, • chest pain, • fainting spells (passing out). 	Get emergency medical help right away

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to do?</p> <p>Get emergency medical help right away if you have any symptoms of changes in your heart rhythm.</p>	
<p>Cough and feeling short of breath</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have a cough and feel short of breath. • Symptoms that commonly occur with a cough are: <ul style="list-style-type: none"> ◦ wheezing or a whistling breathing ◦ runny nose ◦ sore throat ◦ heartburn ◦ weight loss ◦ fever and chills • Rarely this may be severe with chest pain, trouble breathing or coughing up blood. <p>What to do?</p> <ul style="list-style-type: none"> • Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?". • If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. • If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	<p>Talk to your health care team. If you are not able to talk to your health care team for advice, and you have a fever or severe symptoms, you MUST get emergency medical help right away</p>
<p>Allergic reaction</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Fever, itchiness, rash, swollen lips, face or tongue, chest and throat tightness. • It may happen during or shortly after your treatment is given to you and may be severe. 	<p>Get emergency medical help right away for severe symptoms</p>

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>What to do?</p> <ul style="list-style-type: none"> • Tell your nurse right away if you feel any signs of allergic reaction during or just after your treatment. • Talk to your health care team for advice if you have a mild skin reaction. 	
<p>Hemorrhoids</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have swollen veins (blood vessels) around the anus that cause pain or bleeding during or after bowel movements (poo). • Pain and irritation around your anus, • Swelling or a hard lump around your anus • Itching <p>What to do?</p> <p>To help reduce your symptoms:</p> <ul style="list-style-type: none"> • Sit in plain, warm water in a bathtub several times a day. • Use ice packs to reduce swelling. • Be active. Aim to get 20-30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. • Your health care team may instruct you to use hemorrhoid creams or medicines inserted into your rectum (suppositories). • Your health care team may suggest that you add more fibre and fluids to your diet to help soften your stools. 	Talk to your health care team if it does not improve or if it is severe
<p>Increased sweating</p> <p>To help prevent sweating :</p> <ul style="list-style-type: none"> • Avoid triggers such as alcohol, caffeine (tea, coffee, cola), chocolate, hot & spicy food, stress and heat. • Keep cool and dress lightly or in layers that you can remove. Wear clothes made with natural, breathable materials. • Bathe daily. • Drink plenty of liquids unless you are on liquid restriction. • It may improve over time. 	Talk to your health care team if it does not improve or if it is severe

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p>Trouble Sleeping</p> <p>Your medications may cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends.</p> <p>What to look for?</p> <ul style="list-style-type: none"> You may find it hard to fall asleep or stay asleep. How well you sleep may change over your treatment. For example, you may have several nights of poor sleep followed by a night of better sleep. You may wake up too early or not feel well-rested after a night's sleep. You may feel tired or sleepy during the day. <p>What to do?</p> <p>Talk to your health care team if it does not improve or if it is severe</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

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:

- pain, swelling and hardening of a vein
- severe shortness of breath, labored and unusually rapid breathing, low blood pressure and extreme tiredness
- yellowish skin or eyes, unusually dark pee or pain on the right side of your belly
- fever, confusion, weight gain that is not normal for you
- pain in your lower back, swelling in your hands, ankles, feet or other areas of your body, changes in urination (peeing) such as less urine than usual
- muscle twitches and cramps or itchiness that won't go away
- if you have an intravenous (IV) line: swelling, pain, redness or change in skin colour around the IV line.

midostaurin

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.