

ORAL CHEMOTHERAPY EDUCATION



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MIDOSTAURIN

Name of your medication

Generic name — midostaurin (MY-doh-STAW-rin)
Brand name — Rydapt® (RY-dapt)

Common uses

Midostaurin is used to treat adult patients with a type of acute myeloid leukemia, and other blood cell disorders.

Midostaurin may also be used for other treatments.

Dose and schedule

Taking midostaurin as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of midostaurin is 50 milligrams (50 mg) or 100 mg to be taken by mouth at a scheduled time twice a day.
- Midostaurin should be taken with food at the same time each day.
- Midostaurin should be taken whole and not opened, crushed, cut, or dissolved. If you are unable to swallow midostaurin, talk to your care provider or pharmacist for possible options.
- If you miss a dose of midostaurin, **do not** take an extra dose or two doses at one time. Simply take the next dose at the regularly scheduled time.
- Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Storage and handling

Handle midostaurin with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store midostaurin at room temperature (68°F–77°F) in a dry location away from light.
- Keep midostaurin out of reach of children and pets.
- Leave midostaurin in the provided packaging until it is ready to be taken.
- Whenever possible, give midostaurin to yourself and follow the steps below. If a family member, friend, or caregiver needs to give midostaurin to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the midostaurin from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



MIDOSTAURIN

5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- A daily pill box or pill reminder is not recommended to be used with midostaurin.
 - If you have any unused midostaurin, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of midostaurin.
 - If you are traveling, put your midostaurin in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Drug and food interactions

- Midostaurin has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Grapefruit or grapefruit juice may interact with midostaurin; avoid eating or drinking these during treatment with midostaurin.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Side Effects of Midostaurin

The common side effects that have been known to happen in more than 30% of patients taking midostaurin are listed in the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Decreased white blood cells (WBCs) and increased risk for infection	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk for having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none">• Wash your hands often, especially before eating and after using the bathroom.• Avoid crowds and people with fevers, flu, or other infection.• Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none">• Fever (temperature more than 100.4°F or 38°C)• Chills• Sore or scratchy throat• Burning with urination• Unusual tiredness• A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for fever or chills.</p>

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



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MIDOSTAURIN

Possible Side Effect	Management
<p>Nausea or vomiting</p>	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help.</p>
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • High glucose levels • Low calcium levels • High lipase levels • High uric acid levels • Low sodium levels 	<p>Changes in some laboratory values may occur and should be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Bleeding or bruising

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



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MIDOSTAURIN

Possible Side Effect	Management
<p>Mouth irritation or sores</p>	<p>Practice good mouth care.</p> <ul style="list-style-type: none"> • Rinse your mouth frequently. • Brush your teeth with a soft toothbrush or cotton swab after meals. • Use a mild nonalcohol mouth rinse at least four times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. • If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored using a blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your healthcare provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water/fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



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MIDOSTAURIN

Possible Side Effect	Management
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently, and do not pick your nose. • Brush your teeth gently with a soft toothbrush, and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include the following:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than five minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, observe blood in your urine or stool, cough up blood, or experience prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>
<p>Headache</p>	<p>Ask your provider what you may use to help with this discomfort. Contact your care provider right away if your headache:</p> <ul style="list-style-type: none"> • Follows a head injury • Is severe, especially if it starts suddenly • Does not go away after three days • Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, made worse by coughing or lowering the head, rash, weakness in an arm or leg, or numbness
<p>Fluid retention or swelling</p>	<ul style="list-style-type: none"> • Do not stand for long periods of time. • Keep your legs elevated when sitting or lying down. • Avoid eating salty foods, which can increase swelling. • Avoid wearing tight-fitting clothing and shoes. • Weigh yourself daily. <p>Contact your care provider if you notice:</p> <ul style="list-style-type: none"> • Swelling in the hands, feet, or legs • Shortness of breath • Weight gain of five pounds or more in a week

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



MIDOSTAURIN

Possible Side Effect	Management
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none">• Stay as active as possible, but know it is okay to rest as needed.• Try to do some activity every day.• Plan your activities, and do them at a time of day when you feel a bit more energetic.• Avoid operating heavy machinery if you feel too tired.
Abdominal pain	<p>Abdominal pain or discomfort may occur. Report any serious pain or symptoms to your care provider immediately.</p>
Muscle or joint pain	<ul style="list-style-type: none">• Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts.• Stay as active as possible, but know that it is okay to rest as needed, too.• Tell your care provider if pain or a spasm interferes with your activity. <p>If the pain bothers you, ask your provider what you may use to help with this discomfort. Take pain medication only that has been prescribed or recommended by your care provider.</p>

Serious side effects

- Midostaurin may cause your lung tissue to scar which is called interstitial lung disease. Call your care team if you are feeling short of breath, have a fever, or have a lasting dry cough.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since midostaurin remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take midostaurin, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



MIDOSTAURIN

- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or midostaurin with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking midostaurin. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 4 months after the last dose of midostaurin.
- Do not breastfeed while taking midostaurin and for 4 months after the last dose of midostaurin.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on midostaurin, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about how to obtain your midostaurin.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.us.rydapt.com>

Product prescribing information: https://www.novartis.com/us-en/sites/novartis_us/files/rydapt.pdf

Product resources: <https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance/patient-assistance-foundation-enrollment>

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Additional instructions

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



MIDOSTAURIN

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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