

Midostaurin (Rydapt)

About This Medicine

MIDOSTAURIN (mi doe STOR in) treats blood and bone marrow cancers. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Abnormal electrocardiogram (EKG/ECG)
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Nausea and throwing up (vomiting)
- Diarrhea (loose bowel movements)
- Constipation (not able to move your bowels)
- Pain in your abdomen
- Tiredness
- Swelling of the hands, feet, or any other part of the body
- Catheter-related infection
- Fever and neutropenic fever. A type of fever that can develop when you have a very low number of white blood cells which can be life-threatening.
- Blood sugar levels may change
- Bone and muscle pain
- Headache
- Nosebleed
- Trouble breathing
- Upper respiratory tract infection
- Tiny red spots on the skin, often from low platelets

Note: Each of the side effects above was reported in 20% or greater of people treated with midostaurin. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Inflammation (swelling) and/or scarring of the lungs, which may be life-threatening. You may have a cough and/or trouble breathing.

Important Information

- Let your care team know right away if you think you may be pregnant during treatment or if you have been exposed to midostaurin during pregnancy directly, or through a male partner receiving treatment with midostaurin. There is a pregnancy registry which monitors the effect of this medicine on your pregnancy. It is recommended that you or your care team contact the Novartis Pharmaceutical Corporation.

How to Take Your Medicine

- Swallow the medicine whole with food. Do not open or crush the capsules.
- **Missed dose:** If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time, instead, continue with your regular dosing schedule.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Protect from moisture. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- Check the site of your catheter for redness, tenderness, warmth, swelling or abnormal drainage.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.



- If you have a nosebleed, sit with your head tipped slightly forward. Apply pressure by lightly pinching the bridge of your nose between your thumb and forefinger. Call your care team if you feel dizzy or faint or if the bleeding doesn't stop after 10 to 15 minutes.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your care team about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.

Food and Medicine Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine as it may raise the levels of midostaurin in your body which could make side effects worse.
- Check with your care team or about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with midostaurin. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking midostaurin as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Redness, tenderness, drainage, warmth around the catheter site



- Headache that does not go away
- Nosebleed that doesn't stop bleeding after 10-15 minutes
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Any new tiny red spots on the skin
- Pain in your chest
- Wheezing and/or trouble breathing
- Coughing up yellow, green, or bloody mucus
- Dry cough
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Tiredness and/or extreme weakness that interferes with your daily activities
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your mouth or throat that makes it hard to eat or drink
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable.
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Pain in the abdomen or general pain that does not go away, or is not relieved by prescribed medicines
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, trouble urinating, burning or pain when you pass urine, redness and/or swelling of the skin

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 4 months after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 4 months after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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