

Midostaurin (Rydapt)

About This Drug

Midostaurin is used to treat cancer. It is given orally (by mouth).

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 (unable to move your bowels)
- Pain in your abdomen
- Tiredness
- Swelling of the hands, feet, or any other part of the body
- Catheter-related infection
- 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 patients treated with midostaurin. Your side effects may be different based on your condition and dosage of midostaurin. Not all possible side effects are included above.

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 doctor 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 exposure registry which monitors the effect of this drug on your pregnancy. It is recommended that you contact the Novartis Pharmaceutical Corporation at 1-888-669-6682 and/or at <https://psi.novartis.com>

How to Take Your Medication

- 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 and contact your physician.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature. Protect from moisture.
- **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 medication 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 nurse or your doctor 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 doctor or nurse 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 doctor'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 doctor 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 plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 nurse or doctor 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 nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.

Food and Drug 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 doctor or pharmacist 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 drug interactions with midostaurin. Also, check with your doctor or pharmacist 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 drug in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse 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 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
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 4 months after treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 4 months after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 4 months after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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