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Midostaurin

pronounced as (mye"doe staw' rin)

Why is this medication prescribed?

Midostaurin is used with other chemotherapy drugs to treat certain types of acute myeloid leukemia (AML; a type of cancer of the white blood cells). Midostaurin is also used to certain types of mastocytosis (a blood disorder in which there are too many mast cells [a certain kind of white blood cell]). Midostaurin is in a class of medications called kinase inhibitors. It works by blocking the action of the abnormal protein that signals cancer cells to multiply. This helps stop the spread of mast and cancer cells.

How should this medicine be used?

Midostaurin comes as a capsule to take by mouth. It is usually taken with food twice a day. Take midostaurin at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take midostaurin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not open or crush them.

If you vomit after taking midostaurin, do not take another dose. Continue your regular dosing schedule.

Your doctor may decrease your dose of midostaurin or tell you to stop taking midostaurin for a period of time or permanently during your treatment. This depends on the side effects you experience. Talk to your doctor about how you are feeling during your treatment. Continue to take midostaurin even if you feel well. Do not stop taking midostaurin without talking to your doctor.

Your doctor may tell you to take medication to prevent nausea and vomiting before each dose of midostaurin.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking midostaurin,

- tell your doctor and pharmacist if you are allergic to midostaurin, any other medications, or any of the ingredients in midostaurin capsules. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: boceprevir (no longer available in the U.S.; Victrelis); carbamazepine (Carbatrol, Equetro, Tegretol, others); clarithromycin (Biaxin, in Prevpac); diltiazem (Cardizem, Cartia, Tiazac, others); enzalutamide (Xtandi); idelalisib (Zydelig); itraconazole (Onmel, Sporanox); ketoconazole (Nizoral); medications used to treat human immunodeficiency virus (HIV) such as cobicistat (Tybost, in Evotaz, in Genvoya, in Prezcofix, in Stribild), elvitegravir (Vitekta), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra, in Technivie, in Viekira), saquinavir (Invirase) and tipranavir (Aptivus); mitotane (Lysodren); nefazodone; phenytoin (Dilantin, Phenytek); posaconazole (Noxafil); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); troleandomycin (not available in the U.S.); and voriconazole (Vfend). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with midostaurin, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you have or have ever had an irregular heartbeat, QT prolongation (a heart problem that may cause irregular heartbeat, fainting, or sudden death), lung, liver, or kidney disease.
- tell your doctor if you are pregnant or plan to become pregnant. If you are a female, you should not become pregnant while you are taking midostaurin and for up to 4 months after your final dose. You will need to have a negative pregnancy test within 7 days before you start taking midostaurin. Talk to your doctor about birth control methods that will work for you. If you are male, you and your female partner should use birth control during your treatment and continue to use birth control for 4 months after your final dose. If you or your partner become pregnant while taking midostaurin, call your doctor immediately. Midostaurin may harm the fetus.
- tell your doctor if you are breastfeeding. You should not breastfeed while you are taking midostaurin and for 4 months after your final dose.
- you should know that this medication may decrease fertility in men and women.

What special dietary instructions should I follow?

Talk to your doctor about eating grapefruit and drinking grapefruit juice while taking this medication.

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Midostaurin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting

- diarrhea
- headache
- nosebleeds
- tiredness
- weakness
- dizziness
- constipation
- hemorrhoids
- increased sweating
- stomach pain
- white patches or sores on the lips or in the mouth and throat
- swelling of the hands, feet, ankles, or lower legs
- back, bone, joint, limb, or muscle pain
- difficulty falling asleep or staying asleep

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- fever, cough, sore throat, chills, and other signs of infection
- rapid, irregular, or pounding heartbeat
- shortness of breath
- chest pain
- flushing
- swelling of the lips, tongue, or throat
- difficulty breathing or swallowing
- hives
- rash
- itching
- new or worsening cough
- wheezing
- vomiting blood or vomiting material that looks like coffee grounds
- unusual bleeding or bruising
- burning or pain when urinating

Midostaurin may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to midostaurin.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Rydapt[®]

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