

PATIENT INFORMATION
RYDAPT® (rye-dapt)
(midostaurin)
capsules

What is RYDAPT?

RYDAPT is an oral prescription medicine used to treat adults:

- with newly diagnosed with a certain type of acute myeloid leukemia (AML), in combination with certain chemotherapy medicines
 - Your healthcare provider will perform a test to make sure RYDAPT is right for you.
- with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

It is not known if RYDAPT is safe and effective in children.

Do not take RYDAPT if you are allergic to midostaurin or any of the ingredients in RYDAPT. See the end of this leaflet for a complete list of ingredients in RYDAPT.

- Signs and symptoms of an allergic reaction to RYDAPT have included trouble breathing, flushing, chest pain, throat tightness, and swelling of your lips, mouth, or throat. Get medical help right away if you have any of these signs or symptoms.

Before you take RYDAPT, tell your healthcare provider about all of your medical conditions, including if you:

- have any lung or breathing problems
- are pregnant or plan to become pregnant. RYDAPT may cause harm to your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with RYDAPT or think you may be pregnant.
 - If you are able to become pregnant, your healthcare provider may perform a pregnancy test within 7 days before you start RYDAPT.
 - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with RYDAPT and for at least 4 months after the last dose of RYDAPT.
 - **Males** who have female partners that are able to become pregnant should use effective birth control during treatment with RYDAPT and for at least 4 months after the last dose of RYDAPT.
- are breastfeeding or plan to breastfeed. It is not known if RYDAPT passes into your breast milk. You should not breastfeed during treatment with RYDAPT and for at least 4 months after the last dose of RYDAPT.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take RYDAPT?

- Take RYDAPT exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how many capsules of RYDAPT you need to take. Do not change your dose unless your healthcare provider tells you to.
- Your healthcare provider will prescribe medicines to help prevent the nausea and vomiting during treatment with RYDAPT.
- Take RYDAPT 2 times a day (about every 12 hours apart)
- Take RYDAPT with food.
- Do not open or crush RYDAPT capsules.
- If you miss a dose of RYDAPT, take your next dose at your scheduled time. Do not take an extra dose to make up for a missed dose.
- If you vomit after taking a dose of RYDAPT, do not take an extra dose. Take your next dose at your scheduled time.

What are the possible side effects of RYDAPT?

RYDAPT may cause serious side effects, including:

- **Lung problems.** RYDAPT may cause lung problems that may lead to death when used alone or in combination with other chemotherapy medicines. Get medical help right away if you have any new or worsening lung symptoms, including cough, chest discomfort, or shortness of breath.

The most common side effects of RYDAPT in people with AML include:

- low white blood cell counts with fever (febrile neutropenia)
- nausea
- redness, pain or ulcers on the inside your mouth (mucositis)
- vomiting
- headache
- bruising
- muscle or bone pain
- nose bleeds
- device-related infection
- high blood sugar levels (hyperglycemia)
- upper respiratory tract infection

The most common side effects of RYDAPT in people with ASM, SM-AHN, or MCL include:

- nausea
- vomiting
- diarrhea
- swelling in your hands, feet, or ankles
- muscle or bone pain
- stomach-area pain
- tiredness
- upper respiratory tract infection
- constipation
- fever
- headache
- trouble breathing

Call or inform your healthcare provider if nausea, vomiting or diarrhea occurs, gets worse or does not go away.

RYDAPT may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

Your healthcare provider may tell you to decrease your dose, temporarily stop, or completely stop taking RYDAPT if you develop certain side effects during treatment with RYDAPT.

Your healthcare provider will do blood tests to check you for side effects during treatment with RYDAPT.

These are not all of the possible side effects of RYDAPT. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store RYDAPT?

- Store RYDAPT at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep RYDAPT in the original package to protect from moisture.

Keep RYDAPT and all medicines out of the reach of children.

General information about the safe and effective use of RYDAPT.

Medicines are sometimes prescribed for conditions not listed in the Patient Information leaflet. Do not take RYDAPT for a condition for which it was not prescribed. Do not give RYDAPT to other people, even if they have the same condition or symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RYDAPT that is written for healthcare professionals.

What are the ingredients in RYDAPT?

Active ingredient: midostaurin

Inactive ingredients: polyoxyl 40 hydrogenated castor oil, gelatin, polyethylene glycol 400, glycerin 85%, dehydrated alcohol, corn oil mono-di-triglycerides, titanium dioxide, vitamin E, ferric oxide yellow, ferric oxide red, carmine, hypromellose 2910, propylene glycol, and purified water

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For more information about RYDAPT, ask your doctor or pharmacist, visit www.US.RYDAPT.com.

This Patient Information has been approved by the U.S. Food and Drug Administration

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