

UNDERSTANDING AML TREATMENT WITH RYDAPT

INDICATION for RYDAPT[®] (midostaurin) capsules

RYDAPT is an oral prescription medicine used in combination with certain chemotherapy medicines to treat adults with newly diagnosed acute myeloid leukemia (AML) who have a defect in a gene called FLT3. Your doctor will perform a test to make sure RYDAPT is right for you. RYDAPT should not be used alone to induce remission in people with AML.

RYDAPT is not safe when given to children in combination with chemotherapy. It is not known if RYDAPT is effective in children.

IMPORTANT SAFETY INFORMATION for RYDAPT[®] (midostaurin) capsules

Allergic Reactions

- Do not take RYDAPT if you are allergic to midostaurin or any of the ingredients in RYDAPT
- If you develop signs of an allergic reaction, seek medical help immediately
- Signs of an allergic reaction include trouble breathing, flushing, chest pain, throat tightness, and swelling of the face, lips, tongue, or throat

People depicted throughout this brochure are not actual patients.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 10 and 11.

UNDERSTANDING AML

AML is a type of cancer of the blood and bone marrow that primarily affects white blood cells. The DNA in your cells can become altered (or mutated), and when the FLT3 gene is affected, it can play a major role in your cancer's development.

APPROXIMATELY

3 out of 10 patients

with AML have the mutated FLT3 gene



Leukemia cells often reproduce quickly, but in most cases the problem is that they don't die when they should. Acute leukemias, like AML, are fast growing because normal blast cells divide quickly. The leukemia cells don't divide any more often than normal blast cells do. However, they don't stop dividing when normal blast cells would.

IMPORTANT SAFETY INFORMATION (continued)

Pregnancy, Breastfeeding, Fertility

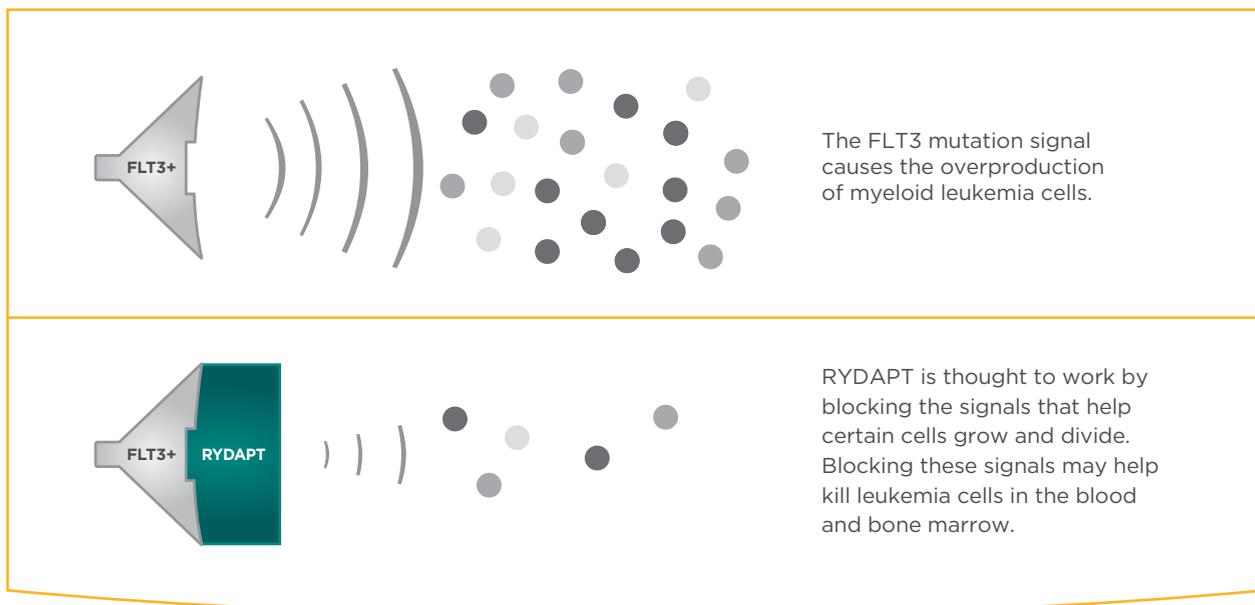
- RYDAPT should not be used during pregnancy since it may harm an unborn baby
- If you become pregnant, think you may be, or are planning to be, tell your doctor right away
- If you are able to become pregnant, your doctor should perform a pregnancy test within 7 days before you start RYDAPT. Effective birth control should be used during treatment and for at least 4 months after the last RYDAPT dose
- Men taking RYDAPT who have female partners who are able to become pregnant should use effective birth control during treatment with RYDAPT and for at least 4 months after the last dose

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WHAT IS RYDAPT?

RYDAPT® (midostaurin) capsules is an oral prescription medicine used in combination with certain chemotherapy medicines to treat adults with newly diagnosed FLT3+ AML.

How RYDAPT works



RYDAPT is the only treatment that is approved by the FDA to treat patients with newly diagnosed AML and the FLT3 mutation, along with chemotherapy.

IMPORTANT SAFETY INFORMATION (continued)

Pregnancy, Breastfeeding, Fertility (cont'd)

- **Pregnancy registry:** There is a pregnancy registry that monitors the health of females and their babies exposed to RYDAPT during pregnancy. Females who have taken RYDAPT during pregnancy, or who have been exposed to RYDAPT during pregnancy through a male partner taking RYDAPT, should contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or at <https://psi.novartis.com>
- Do not breastfeed during treatment with RYDAPT and for at least 4 months after the final dose
- RYDAPT may impair fertility in males and females. You should discuss this with your doctor before starting treatment

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WHAT TO EXPECT FROM TREATMENT

Patients who received treatment with RYDAPT® (midostaurin) capsules plus chemotherapy lived longer than patients who received chemotherapy alone.



**23%
reduction**

in the risk of death compared with standard-of-care chemotherapy alone. A specific median overall survival (the time point at which half the patients were still alive) could not be reliably estimated

GOALS OF TREATMENT	INDUCTION THERAPY	CONSOLIDATION THERAPY
Your doctor will typically start your treatment right away in the hospital. Treatment usually consists of 2 phases.	The goals of induction therapy are to: <ul style="list-style-type: none">• Kill as many leukemia cells as possible• Get your blood counts back to normal• Put your disease in remission* for a period of time	If the disease is still in your body after induction phase, continued treatment may be given in the hospital or as an outpatient.

*Remission means that some of the signs and symptoms of the cancer have disappeared. However, the disease may still be in your body.

IMPORTANT SAFETY INFORMATION (continued)

Lung Problems

- RYDAPT may cause serious lung problems that may lead to death when used alone or in combination with other chemotherapy medicines
- If you develop a new or worsening cough, shortness of breath, or chest discomfort, contact your doctor immediately. These may be signs of serious lung problems

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POSSIBLE SIDE EFFECTS WITH RYDAPT

Your doctor may tell you to decrease your dose, temporarily stop, or completely stop taking RYDAPT® (midostaurin) capsules if you develop certain side effects during treatment with RYDAPT.

Let your doctor know about any side effects you may experience. Be sure to make note of the frequency and intensity. Report severe symptoms to your doctor immediately.



NAUSEA and VOMITING

Your health care provider may prescribe medicines to help prevent nausea and vomiting during treatment with RYDAPT. Take RYDAPT with food.



LOW WHITE BLOOD CELL COUNT WITH FEVER

It's important to have lab work done as directed by your HCP. Additional medication may be prescribed by your doctor to increase your body's production of white blood cells.



INFECTION

Antibiotics or other medications may be prescribed by your doctor to help treat or prevent infection.

These are not the only possible side effects of treatment with RYDAPT therapy. For more information about side effects, please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 10 and 11.

Talk to your doctor before taking any medicine for side effects, such as an over-the-counter treatment for diarrhea.

IMPORTANT SAFETY INFORMATION (continued)

Side Effects

Most common side effects reported during RYDAPT treatment for acute myeloid leukemia (AML) included:

- low level of white blood cells with fever (febrile neutropenia)
- nausea
- redness, pain, or ulcers inside the mouth (mucositis)
- vomiting
- headache
- bruising
- muscle or bone pain
- nose bleeds
- device-related infection
- high blood sugar levels (hyperglycemia)
- upper respiratory infection
- abnormal electrocardiogram (QT prolongation)

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HOW TO TAKE RYDAPT

Make a daily plan to help you remember to take RYDAPT.



TWICE A DAY WITH FOOD

Your doctor will tell you how many capsules you need to take.

The usual starting dose is 50 mg (2 capsules), twice daily (4 capsules total per day), and at approximately 12-hour intervals (with breakfast and with dinner).

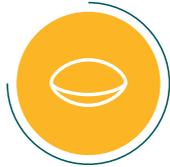
Do not change your dose unless your doctor tells you to.



Take RYDAPT® (midostaurin) capsules exactly as your health care provider instructs.



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.



Do not open or crush RYDAPT capsules.



If you vomit after taking a dose of RYDAPT, do not take an extra dose. Take your next dose at your scheduled time.

Your doctor may prescribe additional medicines to help with nausea and vomiting, if necessary.

How should I store RYDAPT?

- Store RYDAPT at room temperature at 68°F to 77°F (20°C to 25°C)
- Keep RYDAPT in the original container to protect from moisture
- **Keep RYDAPT and all medicines out of the reach of children**

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CARE FROM FAMILY AND FRIENDS

How caregivers can help

Your role as a caregiver is an important one—you are not only a source of support and comfort, but also an advocate for your loved one with newly diagnosed FLT3+ AML. The following are some tips that may be useful while you're helping your loved one through this time:



Tracking treatment-related info/appointments

Keep track of the contact information for your loved one's health care team along with important information about medicines, dosages, symptoms, and side effects treatments.



Insurance/financial resources

Learn more about RYDAPT NOW, brought to you by Novartis Patient Assistance Now Oncology, on the following pages, and visit www.RYDAPT-NOW.com to learn how to enroll.



Staying positive

Patient advocacy groups can put you in touch with others who are going through a similar situation.



Making time for yourself

Remember to take time to relax and continue to eat right and stay active.

IMPORTANT SAFETY INFORMATION (continued)

Side Effects (cont'd)

- If side effects including nausea, vomiting, and diarrhea occur, get worse, or do not go away during treatment with RYDAPT, you should contact your doctor immediately. Your doctor may need to decrease your dose, temporarily stop, or completely stop your treatment with RYDAPT
- These are not all of the possible side effects of RYDAPT. For more information, ask your doctor or pharmacist

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WHAT IS RYDAPT NOW?

Novartis is your partner for access and financial support

RYDAPT NOW offers support with insurance verification in more than 160 languages to help you understand how to get your medicine and what your financial responsibilities are, by:



Assisting you with access to RYDAPT as you transition between inpatient and outpatient settings



Helping you find a pharmacy based on your insurance plan and getting your medicine according to your plan's guidelines



Offering support with insurance verification to help you understand how to get your medicine and what your financial responsibilities are

- Providing information about prior authorization requirements
- Initiating a benefits investigation in the inpatient setting in preparation for transitioning to the outpatient setting



Providing information about financial assistance that may be available

No purchase of RYDAPT® (midostaurin) capsules is required. Novartis cannot guarantee that patients who enroll in **RYDAPT NOW** will be successful in obtaining insurance coverage for treatment or will receive financial assistance.

Novartis Oncology Universal Co-pay Program



You may be eligible for immediate co-pay savings on your next prescription of RYDAPT.

- Commercially insured patients have no co-pay charge*
- Novartis will pay the remaining co-pay, up to \$15,000 per calendar year

***Limitations apply.** Patient must have commercial insurance. Offer is not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full terms and conditions, visit www.Copay.NovartisOncology.com or call **1-877-577-7756**.



To find out if you are eligible for the Novartis Oncology Universal Co-pay Program, call **1-877-577-7756** or visit www.Copay.NovartisOncology.com.

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HOW TO ENROLL IN RYDAPT NOW



Access
RYDAPT NOW online at
www.RYDAPT-NOW.com
and download the
Service Request Form



Complete the Service
Request Form with
your health care
provider and fax it to
1-888-891-4924

OR



Call **1-800-282-7630**
from 9 AM to 8 PM ET,
Monday through Friday,
to begin the
enrollment process

Ask about 1-on-1 Nurse Navigators who can help support you on your treatment journey in addition to enrolling in **RYDAPT NOW**.

Free Supply Program for appropriate patients with AML

If your doctor prescribes RYDAPT for newly diagnosed FLT3+ AML based on the approved label and there is a delay in your insurance coverage as you transition out of the hospital, you may be eligible to receive a free 14-day supply of RYDAPT shipped directly to your home to avoid disruption in your treatment.

IMPORTANT SAFETY INFORMATION (continued)

Taking Other Medicines With RYDAPT

- Before taking RYDAPT, you should tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. RYDAPT may affect how these medicines work, or these other medicines may affect how RYDAPT works
- You should also tell your doctor if you are already taking RYDAPT and are prescribed a new medicine that you have not taken previously during RYDAPT treatment

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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SUMMARY OF IMPORTANT INFORMATION FOR RYDAPT® (MIDOSTAURIN) CAPSULES

What is RYDAPT?

RYDAPT is a prescription medicine used to treat adults:

- 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

RYDAPT is not safe when given to children in combination with chemotherapy. It is not known if RYDAPT is effective in children.

Do not take RYDAPT if you are allergic to midostaurin or any of the ingredients in RYDAPT. See page 11 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

Pregnancy Registry: There is a pregnancy registry that monitors the health of females and their babies exposed to RYDAPT during pregnancy. Females who have taken RYDAPT during pregnancy or have been exposed to RYDAPT during pregnancy through a male partner taking RYDAPT should contact Novartis Pharmaceuticals Corporation at 1-888-669-6682, or at <https://psi.novartis.com/>

- 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

SUMMARY OF IMPORTANT INFORMATION FOR RYDAPT® (MIDOSTAURIN) CAPSULES

- 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 of your mouth (mucositis)
- vomiting
- headache
- bruising
- muscle or bone pain
- nose bleeds
- device-related infection
- high blood sugar levels (hyperglycemia)
- upper respiratory tract infection
- abnormal electrocardiogram (QT prolongation)

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 the FDA at 1-800-FDA-1088.

How should I store RYDAPT?

- Store RYDAPT at room temperature at 68°F to 77°F (20°C to 25°C)
- Keep RYDAPT in the original container 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: carmine, corn oil mono-di-triglycerides, dehydrated alcohol, ferric oxide red, ferric oxide yellow, gelatin, glycerin 85%, hypromellose 2910, polyethylene glycol 400, polyoxyl 40 hydrogenated castor oil, propylene glycol, purified water, titanium dioxide, and vitamin E.



Questions to ask your doctor

- What symptoms or side effects should I tell my doctor about right away?
- How will I know if my treatment with RYDAPT[®] (midostaurin) capsules is working?
- What if I forget to take RYDAPT?
- Do I need to change my diet during treatment with RYDAPT?
- What monitoring is required while I'm taking RYDAPT?
- What if I stop taking RYDAPT?
- What if I take too much RYDAPT?
- How long will I need to stay on RYDAPT?
- What should I know about RYDAPT while sexually active?
- What if I'm pregnant or lactating, or plan on becoming pregnant?
- How will taking RYDAPT at home be different than taking it in the hospital?

INDICATION for RYDAPT[®] (midostaurin) capsules

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