ADVANCED SYSTEMIC MASTOCYTOSIS* AND RYDAPT. YOUR TREATMENT PLAN MADE CLEAR.

*Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL) are collectively referred to as advanced systemic mastocytosis (SM).

PATIENT TREATMENT GUIDE

INDICATION for RYDAPT® (midostaurin) capsules
RYDAPT is an oral prescription medicine used to treat adults with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
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

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

Please see additional Important Safety Information throughout and at the end of this guide. Please click here for full Prescribing Information.
RYDAPT® (midostaurin) 25 MG CAPSULES

APPROVED USE

RYDAPT is an oral prescription medicine used to treat adults with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). 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 (cont’d)

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

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WHAT IS ADVANCED SYSTEMIC MASTOCYTOSIS (ADVANCED SM)?
Advanced SM is a group of rare mast cell disorders where the disease has spread to more than one part of your body, and is stopping your body from working.

WHAT IS RYDAPT?
RYDAPT® (midostaurin) capsules is an oral prescription medicine used to treat adults with advanced SM. RYDAPT is the only FDA-approved treatment for advanced SM, including for those patients with a certain mutation known as the KIT D816V mutation.

STARTING TREATMENT WITH RYDAPT
Treatment with RYDAPT has been shown to help patients with advanced SM treat their condition over time.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)
Pregnancy, Breastfeeding, Fertility (cont’d)
• 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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HOW RYDAPT WORKS

In advanced SM, the KIT mutation causes the overproduction of a type of immune cell called a “mast” cell. “Mastocytosis” means there are too many abnormal mast cells.

RYDAPT helps to slow or shut down the KIT signal

WHAT TO EXPECT FROM TREATMENT

Too many abnormal mast cells can cause damage to your organs, like your kidneys. By reducing the number of abnormal mast cells in your body, treatment with RYDAPT® (midostaurin) capsules can help to relieve the uncomfortable symptoms of advanced SM.

In addition, RYDAPT helped to reduce and even reverse some of the damage in bone marrow caused by mastocytosis. Remember that study results may differ for individual patients. However, with RYDAPT, your doctor has given you a proven way to treat advanced SM.

WHO SHOULD TAKE RYDAPT?

RYDAPT is only for patients diagnosed with advanced SM, which includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).

Note: If you are pregnant or are planning to become pregnant, it’s important to let your doctor know before starting any treatment.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

Lung Problems

• RYDAPT may cause serious lung problems that may lead to death when used alone or in combination with other chemotherapy medicines

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HOW TO TAKE RYDAPT

Make a daily plan to help you remember to take RYDAPT

Your doctor will tell you how many capsules you need to take.
The usual starting dose is 4 capsules, twice a 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 medicines to help prevent nausea and vomiting during treatment

If you have any sides effects, or have any questions, make sure to contact your doctor’s office. Your doctor may prescribe a remedy or revise your treatment plan.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

Lung Problems (cont’d)

• 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

SOME TIPS TO HELP MANAGE SIDE EFFECTS

While taking RYDAPT® (midostaurin) capsules, you may experience side effects. Here are a few suggestions that may help.

NAUSEA AND VOMITING
Avoid foods that may cause upset stomach, like fried or spicy foods. Try to eat more fruits and vegetables.

SWELLING
Limit salt in your diet, and practice light exercise to improve circulation.

DIARRHEA
Stay hydrated by drinking plenty of water. Eat small meals that are easy on the stomach.

FATIGUE
Create a schedule that includes rest time and light activity.

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

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

SIDE EFFECTS
Most common side effects reported during RYDAPT treatment for aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) included:
- nausea
- vomiting
- diarrhea
- swelling of the hands, feet, or ankles
- muscle or bone pain
- stomach-area pain
- tiredness
- upper respiratory infection
- constipation
- fever
- headache
- trouble breathing

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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:

- Providing information about prior authorization requirements
- Helping you find a pharmacy based on your insurance plan, and get your medicine according to your plan’s guidelines
- Providing information about financial assistance that may be available

Novartis cannot guarantee that patients who enroll in RYDAPT NOW will be successful in obtaining insurance coverage for treatment or will receive financial assistance.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

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

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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

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 ADVANCED SM

If you are prescribed RYDAPT® (midostaurin) capsules, for advanced SM, you may be eligible to receive a free 28-day supply of RYDAPT shipped directly to your home or another convenient location, allowing you to begin therapy quickly. No purchase of RYDAPT is required.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

SIDE EFFECTS (cont’d)

● These are not all of the possible side effects of RYDAPT. For more information, ask your doctor or pharmacist

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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 Universal Co-Pay Program, call 1-877-577-7756 or visit www.CoPay.NovartisOncology.com.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

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.

Please see the full Prescribing Information and the FDA-approved Patient Information for RYDAPT® (midostaurin) capsules.

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TIPS AND RESOURCES FOR FAMILY AND FRIENDS

Enlisting a trusted caregiver may make your treatment experience an easier one. Here are a few ways they can help:

- Remind you to take your medication as directed by your doctor
- Keep your doctor up to date on any changes in your overall condition
- Take notes at your doctor appointments and act as your advocate
- Help you navigate insurance claims and payments
- Call RYDAPT Patient Support on your behalf

ADDITIONAL SUPPORT

The Mastocytosis Society, Inc. is a non-profit organization dedicated to supporting patients affected by mastocytosis and Mast Cell Activation Diseases as well as their families, caregivers, and physicians through research, education, and advocacy.

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules

Allergic Reactions

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SUMMARY OF FREQUENT QUESTIONS

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 my RYDAPT?

Do I need to change my diet during treatment with RYDAPT?

What if I stop taking my RYDAPT?

What if I take too much RYDAPT?

How long will I need to stay on RYDAPT?

What should I know about taking RYDAPT while sexually active?

What if I’m pregnant or lactating, or plan on becoming pregnant?

IMPORTANT SAFETY INFORMATION for RYDAPT® (midostaurin) capsules (cont’d)

Allergic Reactions (cont’d)

- Signs of an allergic reaction include trouble breathing, flushing, chest pain, throat tightness, and swelling of the face, lips, tongue, or throat

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IMPORTANT SAFETY INFORMATION

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- headache
- trouble breathing
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- stomach-area pain
- tiredness
- upper respiratory infection
IMPORTANT SAFETY INFORMATION (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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