RYDAPT®
midostaurin 25 mg capsules

People depicted throughout this brochure are not actual patients.

UNDERSTANDING ADVANCED SM* TREATMENT WITH RYDAPT

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

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

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

STARTING TREATMENT WITH **RYDAPT**

Treatment with RYDAPT has been shown to help adults with advanced systemic mastocytosis (SM), which includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).

WHAT IS **RYDAPT**?

RYDAPT® (midostaurin) capsules is a type of oral prescription medication known as a protein kinase inhibitor. Protein kinases are enzymes that send signals to help cells grow and divide. In some types of cancer, these kinase enzymes are too active or are found at levels that are too high. Blocking them may help keep cancer cells from growing.

RYDAPT is thought to block the action of some kinases of abnormal cells, including KIT, and helps to stop their division and growth. RYDAPT is also thought to block the release of histamines that may be causing some of the symptoms of advanced SM.

of advanced SM cases are caused by a mutation in a gene known as "KIT."

RYDAPT is the first and only FDA-approved treatment of its kind for advanced SM.

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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RYDAPT® midostaurin 25 mg capsules

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.

The KIT mutation causes mastocytosis.

RYDAPT is thought to work by slowing or stopping the KIT signal, which helps control the growth of abnormal mast cells.

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

Too many abnormal mast cells can cause damage to your organs, like your liver.

Mast cells can change and grow out of control in your body. SM symptoms occur when too many mast cells are made in the bone marrow and enter organs like the liver or spleen, or release substances like histamine into the blood.

Treatment with RYDAPT® (midostaurin) capsules can reduce the number of mast cells in your body. RYDAPT is also thought to block the release of the histamines that may be causing some of the symptoms of advanced SM.

Keep in mind that study results may differ for individual patients.

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

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

RYDAPT® midostaurin 25 mg capsules

HOW TO TAKE **RYDAPT**

Make a daily plan to help you remember to take RYDAPT

(Not actual size)

TWICE A DAY
WITH FOOD

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 (for example, with breakfast and with dinner).

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

Your doctor will prescribe additional medicines to help with nausea, if necessary.

Take RYDAPT 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.

IMPORTANT SAFETY INFORMATION (continued)

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

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

RYDAPT® midostaurin 25 mg capsules

POSSIBLE SIDE EFFECTS WITH **RYDAPT**

Some tips to help

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.

DIARRHEA

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

SWELLING

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

FATIGUE

Create a schedule that includes rest time and light activity.

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.

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.

For more information, call the RYDAPT Patient Support Line at 1-800-282-7630

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

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

RYDAPT® midostaurin 25 mg capsules

CARE FROM 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. **tmsforacure.org**

TMS
THE MAST CELL DISEASE SOCIETY, INC.

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

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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.

Novartis Oncology Universal Co-pay Program

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

- Commercially insured patients pay $10 per month*
- 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**.

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

RYDAPT® midostaurin 25 mg capsules

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 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 (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.

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

RYDAPT® midostaurin 25 mg capsules

SUMMARY OF IMPORTANT INFORMATION FOR RYDAPT® (midostaurin) capsules

What is RYDAPT?

RYDAPT® (midostaurin) capsules is a 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.

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 health care 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 health care 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 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

  - If you are able to become pregnant, your health care 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 health care 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 health care provider tells you
- Your health care provider will tell you how many capsules of RYDAPT you need to take. Do not change your dose unless your health care provider tells you to
- Your health care provider will prescribe medicines to help prevent 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 ASM, SM-AHN, or MCL include:

- nausea
- vomiting
- diarrhea
- swelling of 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 health care 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 health care provider if you have concerns about fertility.

Your health care 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 health care 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. 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 health care provider for information about RYDAPT that is written for health care 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.

RYDAPT® midostaurin 25 mg capsules

ADVANCED SM CAN BE A DAILY CHALLENGE.

It's important to try to continue on your treatment journey to get the most out of treatment. Seeking support from loved ones, health care providers, and patient advocacy groups can help keep you actively involved in your treatment.

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 (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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