For patients with 3 types of systemic mastocytosis (SM)*

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

A GUIDE TO TREATMENT WHILE TAKING RYDAPT FOR 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).

It is unknown if RYDAPT is safe and effective in children.

IMPORTANT SAFETY INFORMATION for RYDAPT

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 14 and 15.
STARTING YOUR JOURNEY

The process of being diagnosed with advanced SM can be a long and frustrating experience, which often requires multiple visits to a number of different health care providers. Identifying advanced SM can be challenging, and now that you or someone you care about has received a diagnosis, you probably have many questions.

The content in this brochure can help you learn more about a group of diseases called advanced SM and about RYDAPT® (midostaurin) capsules, an oral prescription medicine used to treat advanced SM. Write down any additional questions you have and discuss them with your health care provider and health care team.

Understanding advanced SM

SM is a term that refers to several different disorders, all of which cause the body to produce too many mast cells. These cells play an important role in your immune system and normally help protect the body from disease and aid in wound healing. For example, mast cells release histamine, a chemical that can cause allergic reactions such as itching, hives, or sneezing.

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

Advanced SM is a collective term used to refer to 3 types of SM:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with an associated hematologic neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

How is advanced SM diagnosed?

There are several types of tests that can help doctors determine whether or not someone has advanced SM. These may include blood tests, skin biopsy, and bone-marrow aspiration and biopsy. Examining your biopsy results can help your doctor identify specific genes, proteins, and other factors to determine what kind of treatment may be most appropriate for you.

For example, your doctor may perform a genetic test to look for specific alterations (or mutations) in your cancer cells. One type of mutation that plays a role in advanced SM affects a protein kinase called KIT.

- Approximately 90% of patients with SM have a type of mutation known as KIT D816V.

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
- 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

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 14 and 15.
What is RYDAPT and how can it help treat my advanced SM?

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.

What are the potential benefits of taking RYDAPT?

In a clinical trial of 116 patients with advanced SM, 89 patients were evaluated to assess their response to treatment with RYDAPT.

Overall, 21% of these patients (19 of 89) responded to RYDAPT; response included disease improvement in at least 1 organ.

Patients evaluated included those with and without a KIT D816V mutation:

- 46 of 73 patients with KIT D816V mutation achieved disease improvement in at least 1 organ with RYDAPT (63%)
- 7 of 16 patients with wild-type (not mutant) KIT or unknown KIT mutation status achieved disease improvement in at least 1 organ with RYDAPT (44%)

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

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

IMPORTANT SAFETY INFORMATION (CONTINUED)

About 66% of patients (21 of 32) who had received prior treatment for advanced SM responded to treatment with RYDAPT.

• About 66% of patients (21 of 32) who had received prior treatment for advanced SM responded to treatment with RYDAPT

RYDAPT began to work quickly.

• 21% of patients in the trial (19 of 89 patients) responded to RYDAPT. In half of these patients, RYDAPT began to work in about 2 weeks

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 14 and 15.
The effectiveness of RYDAPT was demonstrated in patients with different subtypes of SM.

In the clinical trial, patients were evaluated to determine whether or not they responded to RYDAPT® (midostaurin) capsules, how long their responses lasted, and how quickly they began to respond.

The results show the effectiveness of RYDAPT in all patients in the clinical trial (regardless of what type of SM they had) and in patients according to their specific subtype of SM.

### CLINICAL TRIAL MEASURE OF RYDAPT EFFECTIVENESS

<table>
<thead>
<tr>
<th>Measure</th>
<th>All patients evaluated (89 patients)</th>
<th>Patients with ASM (16 patients)</th>
<th>Patients with SM-AHN (57 patients)</th>
<th>Patients with MCL (16 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieving a complete or incomplete remission of disease after receiving 6 treatment cycles with RYDAPT</td>
<td>21% (19 of 89 patients)</td>
<td>38% (6 of 16 patients)</td>
<td>16% (9 of 57 patients)</td>
<td>25% (4 of 16 patients)</td>
</tr>
<tr>
<td>Median duration of response ranged from 6.6 months to 65.8 months</td>
<td>Median duration of response ranged from 12.1 months to 36.8 months</td>
<td>Median duration of response ranged from 6.6 months to 52.1 months</td>
<td>Median duration of response ranged from 6.6 months to 65.8 months</td>
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<tr>
<td>Median time (the time point) at which half of the patients began to respond to RYDAPT</td>
<td>0.5 months The median time to response ranged from 0.1 months to 3 months</td>
<td>0.7 months The median time to response ranged from 0.3 months to 1.9 months</td>
<td>0.5 months The median time to response ranged from 0.1 months to 3 months</td>
<td>0.3 months The median time to response ranged from 0.1 months to 0.5 months</td>
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</tbody>
</table>

A specific median duration of response was not reported because, at the time of analysis, more than half of patients receiving RYDAPT were still responding to treatment.

### IMPORTANT SAFETY INFORMATION (CONTINUED)

**Side Effects (Continued)**

- 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 14 and 15.
**QUESTIONS TO ASK YOUR DOCTOR**

It is important to communicate regularly with your health care provider so informed decisions can be made regarding your treatment. Following are a few questions you may want to ask your doctor before beginning treatment. Be sure to bring up any additional questions that may help you better understand how to get the most out of your treatment.

- 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?

**How do I take RYDAPT?**

- Take RYDAPT exactly as your health care provider tells you.
- 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.

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

Taking RYDAPT at the same time each day will help you to remember when to take your medicine.

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

**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.

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CAREGIVERS PLAY AN ESSENTIAL ROLE IN THE LIVES OF PATIENTS WITH ADVANCED SM

When someone learns that they have advanced SM, there is suddenly a lot of information that needs to be processed, as well as practical considerations about scheduling doctor’s appointments and taking medicines. It may be difficult for a patient to absorb all of these details, especially at a time when they’re not feeling well and are experiencing a wide range of emotions.

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. You become their eyes and ears, and are there at doctor’s visits to listen and record information about what can be expected during the treatment journey. You are also the person who helps them stay on track with their treatments and medicines and helps them to meet their basic needs.

As a caregiver, we understand that you’re also dealing with your own emotions, as well as the day-to-day considerations that accompany caring for someone with advanced SM. Here are some tips that may be useful while you’re helping your loved one through this time.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

Keep a notebook with treatment-related information. Be sure to ask questions and take notes during medical appointments so that you can review them later. Keep track of the contact information for your loved one’s health care team, as well as important information about medicines, dosages, symptoms, and side effects of treatments.

Learn about insurance and/or financial resources that may be available. Navigating insurance issues can be challenging, but it’s possible to get help. A doctor and his or her office staff can help you sort out some of the details, and if your loved one is prescribed RYDAPT® (midostaurin) capsules, Novartis has a patient support program for eligible patients. 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.

Try to stay positive. Your outlook can make a big difference in the life of your loved one with advanced SM. Of course, remaining positive isn’t always easy, so seek out advice and support from family members, friends, professional counselors, and doctors. Patient advocacy groups can put you in touch with others who are going through a similar situation.

Make time for yourself. It can be easy to neglect yourself while you’re caring for someone with advanced SM. Be sure to continue to eat right and exercise, and take some time to relax.

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

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 14 and 15.
RYDAPT NOW—YOUR PARTNER FOR ACCESS AND FINANCIAL SUPPORT

On behalf of Novartis Patient Assistance Now Oncology and the whole team at RYDAPT NOW, we are here to help you navigate the path along your treatment journey.

During advanced SM treatment with RYDAPT® (midostaurin) capsules, Care Coordinators are there to support you

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

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

Call 1-800-282-7630 or visit www.RYDAPT-NOW.com for information on how to enroll in RYDAPT NOW and to learn more about the ways we can help.

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 (CONTINUED)

Pregnancy, Breastfeeding, Fertility (Continued)

- 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
- 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

Free Supply Program for appropriate patients with advanced SM

If you are prescribed RYDAPT 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. Novartis cannot guarantee that every patient who enrolls in RYDAPT NOW will be successful in obtaining insurance coverage for treatment.

Novartis Oncology Universal Co-pay Program

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

- Eligible patients with private insurance may pay $10 per month*.
- Novartis will pay the remaining co-pay, up to $15,000 per calendar year.

Terms and Conditions: The Novartis Oncology Universal Co-pay Program includes the co-pay card, payment card, or rebate with a combined annual limit of $15,000. Patient is responsible for any costs once the limit is reached in a calendar year. This offer is only available to patients that are enrolled in Medicare, Medicaid, or any other federal or state health care 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.

$10 CO-PAY

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.

*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients that are enrolled in Medicare, Medicaid, or any other federal or state health care 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.

Patient Instructions: After enrollment in the program, present this card and your insurance card along with a valid prescription at any participating pharmacy or through mail order. Patients are responsible for up to the first $25 (specific offer varies by brand) and Novartis pays up to $15,000 per calendar year. If patient reaches the maximum annual cap per calendar year of $15,000, patient will be responsible for the difference.

When you use this card, you are certifying that you understand and agree to comply with the program Terms and Conditions above.

Direct patient questions to: 1-877-577-7756.

Please see Important Safety Information throughout this brochure and the Summary of Important Information on pages 14 and 15.
SUMMARY OF IMPORTANT INFORMATION

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).

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 page 15 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. 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

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: 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

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.
RYDAPT MAY BE AN IMPORTANT PART OF YOUR TREATMENT JOURNEY

In a clinical study of 116 patients with advanced SM, 89 were evaluated to assess their response to treatment with RYDAPT® (midostaurin) capsules

- Overall, 21% of these patients (19 of 89) responded to RYDAPT; response included disease improvement in at least 1 organ
- RYDAPT showed activity both in patients who had the KIT D816V mutation and in those who did not (wild type)
- About 66% of patients (21 of 32) who had received prior treatment for advanced SM responded to treatment with RYDAPT

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 14 and 15.