

## DISCOVER AYVAKIT® (avapritinib)

Patient Portrayal



Patient Portrayal

#### **IMPORTANT SAFETY INFORMATION**

AYVAKIT<sup>®</sup> (avapritinib) may cause serious side effects, including:

**Cognitive effects.** Cognitive side effects can happen during treatment with AYVAKIT and can be severe. Tell your healthcare provider if you develop any new or worsening cognitive symptoms including forgetfulness, confusion, getting lost, trouble thinking, drowsiness, trouble staying awake (somnolence), word finding problems, seeing objects or hearing things that are not there (hallucinations), or a change in mood or behavior.

## > TAKE A STEP TOWARDS RELIEF

DISCOVER AYVAKIT—THE FIRST AND ONLY FDA-APPROVED TREATMENT TO REDUCE THE SYMPTOMS OF ISM.

This brochure will provide an overview of the risks and benefits of AYVAKIT, how it was studied and how you can get support if you are prescribed AYVAKIT.

#### INDICATION

AYVAKIT<sup>®</sup> (avapritinib) is a prescription medicine used to treat adults with indolent systemic mastocytosis (ISM). AYVAKIT is not recommended in people with low platelet counts (less than 50 X 10<sup>°</sup>/L). It is not known if AYVAKIT is safe and effective in children.





The following information about AYVAKIT may be helpful throughout your treatment journey.



### Discover more at <u>AYVAKIT.com/ISM</u>.

IMPORTANT SAFETY INFORMATION CONTINUED

**Skin sensitivity to sunlight (photosensitivity).** Your skin may be sensitive to the sun or other forms of light (photosensitivity) during treatment with AYVAKIT. Avoid or limit exposure to direct sunlight, sunlamps, and other sources of ultraviolet radiation during treatment and for 1 week after stopping treatment with AYVAKIT. Use sunscreen or wear clothes that cover your skin if you need to be out in the sun.

Please see the full Important Safety Information on pages 30-32 and click here to see the <u>Prescribing Information</u> and <u>Patient Information</u> for AYVAKIT.

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## > WHAT IS ISM?

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## What is indolent systemic mastocytosis (ISM)?

ISM is a rare disease that affects the production and accumulation of abnormal mast cells, a type of white blood cell.

Normally, your body makes mast cells as part of your immune response, but a buildup of abnormal mast cells in different parts of the body can lead to symptoms similar to severe allergic reactions.

### What causes ISM?

In about 95% of cases, ISM is thought to be caused by a gene mutation called KIT D816V.

### How is ISM diagnosed?

ISM is diagnosed by a doctor who may:

- Take biopsies (bone and/or organ)
- Measure signs of excess mast cells
- Test for the KIT D816V gene mutation
- Test for serum tryptase

### KIT D816V testing

A KIT D816V blood test may be helpful to aid in the diagnosis of patients who are being evaluated for ISM. Since the gene mutation is found in approximately 95% of ISM cases, measurement of this genetic marker can help screen for ISM. There are different types of KIT tests available that vary in sensitivity. High sensitivity tests may be required to detect the gene mutation. There are other tests that may be helpful in diagnosing ISM; talk to your doctor about what testing might be most useful for you.

## What are some of the common symptoms of ISM?

While each person with ISM may experience different symptoms in different ways, common symptoms include:



Skin lesions and rash





Potentially severe allergic reactions including anaphylaxis



Nausea, vomiting and diarrhea



vapritinib 25m

#### **IMPORTANT SAFETY INFORMATION CONTINUED**

### Before taking AYVAKIT, tell your healthcare provider about all of your medical conditions, including if you:

- history of bulging or weakening of a blood vessel wall (aneurysm) or bleeding in your brain
- have a history of stroke within the last year
- have low platelet counts
- have or have had liver problems
- are pregnant or plan to become pregnant. AYVAKIT can cause harm to your unborn baby

## HOW AYVAKIT (avapritinib) WORKS

AYVAKIT TARGETS A GENE MUTATION THAT IS AN UNDERLYING CAUSE OF ISM IN ABOUT 95% OF PATIENTS.



### **>** Living with ISM symptoms

You may have been managing symptoms with multiple treatments that help relieve individual symptoms. Before AYVAKIT, there were no FDA-approved therapies for ISM.

### How does AYVAKIT (avapritinib) work?

About 95% of patients with ISM have a gene mutation called KIT D816V. This gene mutation can lead to the uncontrolled growth and buildup of abnormal mast cells, which can lead to symptoms of ISM.

### AYVAKIT works by selectively targeting the KIT D816V gene mutation to help slow the growth of mast cells.

You do not need to have the KIT D816V gene mutation to be prescribed AYVAKIT.



If you are an adult diagnosed with ISM, talk to your doctor to see if AYVAKIT may be able to help reduce your ISM symptoms.



To create a personalized Doctor Discussion Guide, scan the QR code to visit <u>AYVAKIT.com/DDG</u>.



#### IMPORTANT SAFETY INFORMATION CONTINUED

 Females who are able to become pregnant: Your healthcare provider should do a pregnancy test before you start AYVAKIT. You should use effective birth control (contraception) during treatment with AYVAKIT and for 6 weeks after the final dose of AYVAKIT. Talk to your healthcare provider about birth control methods that may be right for you. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with AYVAKIT.



## WHAT AYVAKIT (avapritinib) MAY DO FOR YOU

IMAGINE WHAT'S POSSIBLE WITH A TREATMENT THAT'S PROVEN TO HELP REDUCE ISM SYMPTOMS IN ADULTS.

AYVAKIT

#### **IMPORTANT SAFETY INFORMATION CONTINUED**

- Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment and for 6 weeks after the final dose of AYVAKIT.
- are breastfeeding or plan to breastfeed. It is not known if AYVAKIT passes into your breast milk. Do not breastfeed during treatment with AYVAKIT and for at least 2 weeks after the final dose of AYVAKIT. Talk to your healthcare provider about the best way to feed your baby during this time

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### What to know about AYVAKIT (avapritinib)

### AYVAKIT is clinically proven to help reduce the symptoms of ISM.

The efficacy and safety of AYVAKIT was studied in a randomized, placebo-controlled clinical trial with 212 adults over 24 weeks. Each patient had moderate to severe ISM symptoms, despite taking at least 2 symptom-directed therapies. 141 received AYVAKIT and 71 received placebo. Both AYVAKIT- and placebo-treated patients continued their best supportive care.

In the clinical trial, patients were asked to report the severity of 11 symptoms on a scale from 0 (none) to 10 (worst). These numbers were then combined to produce a total symptom score, a tool used to help measure the efficacy of AYVAKIT.

In the trial, patients taking AYVAKIT plus best supportive care reported a significantly lower total symptom score compared with patients taking placebo plus best supportive care.

#### IMPORTANT SAFETY INFORMATION CONTINUED

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. AYVAKIT may affect the way other medicines work, and certain other medicines may affect how AYVAKIT works. Especially tell your healthcare provider if you take estrogen-containing hormonal birth control or medicines that prevent blood clots.

## AYVAKIT plus best supportive care reduced overall symptoms of ISM

Patients' total symptom score was reduced by 15.3 points with AYVAKIT vs. 9.6 points with placebo at 24 weeks.

AYVAKIT + BEST SUPPORTIVE CARE (N=141)

-15.3

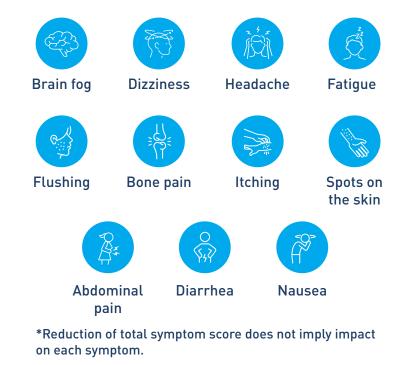
average point reduction in total symptom score PLACEBO + BEST SUPPORTIVE CARE (N=71)

-9.6

average point reduction in total symptom score



# AYVAKIT (avapritinib) plus best supportive care significantly reduced symptoms of ISM<sup>\*</sup>, including:



#### IMPORTANT SAFETY INFORMATION CONTINUED

**Do not** drive or operate hazardous machinery if you have confusion or trouble thinking during treatment with AYVAKIT.

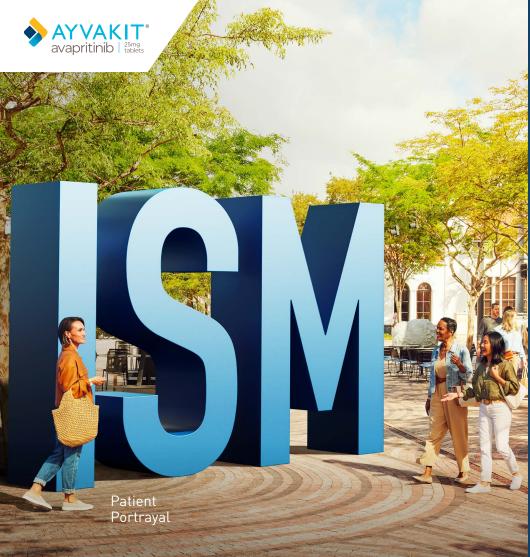
#### The most common side effects of AYVAKIT in people with ISM

**include:** swelling around your eyes, dizziness, swelling of your arms and legs, and flushing.

68% of patients on AYVAKIT plus best supportive care saw a reduction of mutated mast cell (KIT D816V) frequency in their blood by at least half vs. 6% on placebo plus best supportive care at 24 weeks



### To learn more about AYVAKIT results in the clinical trial, visit <u>AYVAKIT.com/ISM</u>.



## > STARTING TREATMENT

DISCOVER WHAT MAY BE POSSIBLE WITH SYMPTOM RELIEF.

#### **IMPORTANT SAFETY INFORMATION**

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AYVAKIT if you develop certain side effects. AYVAKIT may cause fertility problems in females and males. Talk to your healthcare provider if this is a concern for you.



### How do I take AYVAKIT (avapritinib)?





One 25 mg tablet

Taken once a day or as directed



On an empty stomach, at least 1 hour before or at least 2 hours after a meal

### The recommended dose of AYVAKIT is 25 mg orally once daily in adults with ISM.

If you miss a dose of AYVAKIT, take it as soon as you remember, unless your next scheduled dose is due within 8 hours. Then take the next dose at your regular time.

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

#### **IMPORTANT SAFETY INFORMATION CONTINUED**

**Cognitive effects.** Cognitive side effects can happen during treatment with AYVAKIT and can be severe. Tell your healthcare provider if you develop any new or worsening cognitive symptoms including forgetfulness, confusion, getting lost, trouble thinking, drowsiness, trouble staying awake (somnolence), word finding problems, seeing objects or hearing things that are not there (hallucinations), or a change in mood or behavior.

### Your AYVAKIT treatment

Take AYVAKIT exactly as your healthcare provider tells you to take it.

Do not change your dose or stop taking AYVAKIT unless your healthcare provider tells you to.

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### Tips for establishing a treatment routine



Make note of how you're feeling with a daily journal.



Keep your AYVAKIT prescription in a safe place that's easy to spot.



Set a daily alarm to take AYVAKIT.

Take AYVAKIT exactly as prescribed by your doctor. Do not change your dose or stop taking AYVAKIT unless your doctor tells you to. Before taking AYVAKIT, tell your doctor about all of your medical conditions and the medicines you take.

#### IMPORTANT SAFETY INFORMATION CONTINUED

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### Discover a once-daily tablet

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## HELPFUL RESOURCES

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# • Get resources for your treatment journey

You're not alone. YourBlueprint<sup>®</sup> is a personalized patient support program designed to assist eligible patients right from the start of prescribed treatment with AYVAKIT by providing:



**1-on-1 support:** Learn how our team can help support you throughout your treatment journey.



#### Financial assistance options:

You may be eligible for our financial assistance programs if you do not have insurance, your insurance is limited, or you have unaffordable out-of-pocket costs for AYVAKIT.



Helpful resources: Discover other resources that may offer additional support.



For more information, visit <u>YourBlueprint.com</u> or call 1-888-258-7768, Monday-Friday, 8 AM-8 PM Eastern Time (ET)

### Sign up for the Co-Pay Assistance Program

You may be eligible to pay as little as \$0 for your prescription.\*



\*Up to an annual maximum benefit of \$25,000. Terms and conditions apply.

#### For those who qualify, this program covers:

- Co-pay
- Co-insurance
- Deductible expenses

To learn more, read the terms and conditions at <u>YourBlueprint.com/Financial-Assistance</u> or call us at 1-888-BLUPRNT (1-888-258-7768).



### Important Safety Information

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- are pregnant or plan to become pregnant. AYVAKIT can cause harm to your unborn baby
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including prescription and over-the-counter medicines, vitamins, and herbal supplements. AYVAKIT may affect the way other medicines work, and certain other medicines may affect how AYVAKIT works. **Especially tell your healthcare provider** if you take estrogen-containing hormonal birth control or medicines that prevent blood clots.

Please see additional Important Safety Information on page 32.



#### **IMPORTANT SAFETY INFORMATION CONTINUED**

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The most common side effects of AYVAKIT in people with ISM include: swelling around your eyes, dizziness, swelling of your arms and legs, and flushing.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AYVAKIT if you develop certain side effects. AYVAKIT may cause fertility problems in females and males. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of AYVAKIT. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call **1-800-FDA-1088**.

Please click here to see the full <u>Prescribing</u> <u>Information</u> and <u>Patient Information</u> for AYVAKIT.

### Learn more

To sign up for the latest information about AYVAKIT, scan the QR code to visit <u>AYVAKIT.com/Sign-Up</u>.

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## EXPLORE WHAT'S POSSIBLE

Blueprint Medicines is the manufacturer of AYVAKIT. Blueprint Medicines is a precision therapy company focused on genomically defined cancers, rare disease, and cancer immunotherapy, with headquarters in Cambridge, MA.



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