

PATIENT INFORMATION
AYVAKIT® (aye vah kit)
(avapritinib)
tablets, for oral use

What is AYVAKIT?

AYVAKIT is a prescription medicine used to treat adults with:

- a certain type of stomach, bowel, or esophagus cancer called gastrointestinal stromal tumor (GIST) that cannot be treated with surgery or that has spread to other parts of the body (metastatic), and that is caused by certain abnormal platelet-derived growth factor receptor alpha (PDGFRA) genes. Your healthcare provider will perform a test to make sure that you have this abnormal PDGFRA gene and that AYVAKIT is right for you.
- advanced systemic mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).
AYVAKIT is not recommended for the treatment of AdvSM in people with low platelet counts (less than $50 \times 10^9/L$).
- indolent systemic mastocytosis (ISM).
AYVAKIT is not recommended for the treatment of ISM in people with low platelet counts (less than $50 \times 10^9/L$).

It is not known if AYVAKIT is safe and effective in children.

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

- have a history of bulging or weakening of a blood vessel wall (aneurysm) or bleeding in your brain
- 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.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with 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.

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.

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 (contraception)
- medicines that prevent blood clots

How should I take AYVAKIT?

- 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.
- AYVAKIT is usually taken 1 time each day.
- Take AYVAKIT tablet(s) on an empty stomach at least 1 hour before or at least 2 hours after a meal.
- If you miss a dose of AYVAKIT, take it as soon as you remember unless your next scheduled dose is due within 8 hours. 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.

What should I avoid while taking AYVAKIT?

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

What are the possible side effects of AYVAKIT?

AYVAKIT may cause serious side effects, including:

- **Bleeding in your brain.** Serious bleeding in the brain may happen during treatment with AYVAKIT and may lead to death. Stop taking AYVAKIT and tell your healthcare provider right away if you develop any symptoms such as severe headache, nausea, vomiting, vision changes, drowsiness, dizziness, confusion, or severe weakness on one or more side of your body. Bleeding in the brain has not been seen in people treated with AYVAKIT for ISM.
If you have AdvSM, your healthcare provider will check your platelet counts before and during treatment with AYVAKIT.
- **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)
 - change in mood or behavior
- **Skin sensitivity to sunlight (photosensitivity).** See **“What should I avoid while taking AYVAKIT?”**

The most common side effects of AYVAKIT in people with GIST include:

- fluid retention or swelling
- nausea
- tiredness or weakness
- trouble thinking
- vomiting
- decreased appetite
- diarrhea
- increased eye tearing
- stomach area (abdominal) pain
- constipation
- rash
- dizziness
- hair color changes
- changes in certain blood tests

The most common side effects of AYVAKIT in people with AdvSM include:

- fluid retention or swelling
- diarrhea
- nausea
- tiredness or weakness
- changes in certain blood tests

The most common side effects of AYVAKIT in people with ISM include:

- swelling around your eyes
- dizziness
- swelling of your arms and legs
- 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 may report side effects to FDA at 1-800-FDA-1088.

How should I store AYVAKIT?

- Store AYVAKIT tablets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep AYVAKIT and all medicines out of the reach of children.

General information about the safe and effective use of AYVAKIT.

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not take AYVAKIT for a condition for which it was not prescribed. Do not give AYVAKIT to other people, even if they have the same condition that you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about AYVAKIT that is written for health professionals.

What are the ingredients in AYVAKIT?

Active ingredient: avapritinib

Inactive ingredients: copovidone, croscarmellose sodium, magnesium stearate, and microcrystalline cellulose.

Film coat: polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Blue printing ink (100 mg, 200 mg and 300 mg tablets only): ammonium hydroxide, black iron oxide, esterified shellac, FD&C blue 1, isopropyl alcohol, n-butyl alcohol, propylene glycol, and titanium dioxide.

Manufactured for: Blueprint Medicines Corporation, Cambridge, MA 02139, USA

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For more information, go to www.AYVAKIT.com or call 1-888-258-7768.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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