

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.

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:

- 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. Talk to your healthcare provider prior to starting a new medicine.

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.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with AYVAKIT if you develop side effects.
- Take AYVAKIT 1 time each day.
- Take AYVAKIT tablet(s) on an empty stomach at least 1 hour before and 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.

What are the possible side effects of AYVAKIT?

AYVAKIT may cause serious side effects, including:

- **Bleeding in your brain.** Stop taking AYVAKIT and tell your healthcare provider if you develop any symptoms such as severe headache, vision problems, severe sleepiness, severe weakness on one side of your body.
- **Central nervous system (CNS) effects.** CNS side effects are common with AYVAKIT and can be severe. Tell your healthcare provider if you develop any new or worsening CNS symptoms including:
 - forgetfulness
 - confusion
 - getting lost
 - trouble thinking
 - drowsiness
 - dizziness
 - trouble sleeping
 - word finding problems
 - seeing objects or hearing things that are not there (hallucinations)
 - change in mood or behavior

Your healthcare provider may temporarily stop treatment or decrease your dose which may help your symptoms improve. If symptoms do not improve, your healthcare provider may permanently stop treatment with AYVAKIT.

The most common side effects of AYVAKIT include:

- fluid retention or swelling
- nausea
- tiredness
- muscle weakness
- vomiting
- diarrhea
- decreased appetite
- stomach area (abdominal) pain
- increased eye tearing
- constipation
- rash
- dizziness
- hair color changes

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: 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.