Avapritinib AYVAKYT®

Patient information sheet V3.1, December 2024



WHAT IS AYVAKYT® AVAPRITINIB?

- A targeted therapy used to treat some blood cancers and some gastrointestinal cancers.
- Prescribed and renewed by your hospital-based oncologist, cancer specialist or internal medicine doctor.
- Available from community pharmacies on presentation of your prescription.



- White tablet with "BLU" in blue on one side and the dosage on the other.
- 5 dosages available: **25 mg** (round), **50 mg** (round), **100 mg** (round), **200 mg** (oval) or **300 mg** (oval)



Do not store above 25°C, and keep out of the sight and reach of children.



Do not take the tablets out of the bottle to put them in a pillbox.

Wash your hands carefully before and after handling the tablets.



Do not throw away opened bottles, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?

.....**:**.....

= 1 dose per day at a set time

not at mealtimes (at least one hour before and two hours after a meal)

How?



Swallow the tablets whole, with water, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **medical diary*** and a **calendar** to note doses.

Do not stop taking or change how you take your treatment without consulting your doctor.

** This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT



- If it has been less than 16 hours since your dose was due: take the missed dose. Take your next dose at the usual time. Keep a record in your medical diary*.
- If it has been more than 16 hours since your dose was due, do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.
- If you throw up, do not take another dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit** and **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect effectiveness and the occurrence of side effects.



- You and your partner must use effective methods of contraception (condoms and another method)
 throughout treatment and for 6 weeks after the last dose for women of child-bearing age and 2 weeks
 after the last dose for men.
- Stop breastfeeding during treatment and for 2 weeks after the last dose.

*Patient diary available (in French) at <u>www.omedit-fiches-cancer.fr</u>

WHAT SIDE EFFECTS CAN OCCUR WITH AYVAKYT® AVAPRITINIB?

Like all medicines, avapritinib may cause side effects, although not everybody gets them.

Side effects

Prevention

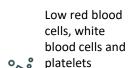


Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.



Digestive effects: constipation, diarrhoea, nausea, vomiting

Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of constipation, eat foods rich in fibre (bran, grains, wholemeal bread, green vegetables, fruit and nuts) and exercise regularly. In case of diarrhoea, eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). In case of nausea/vomiting, divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.



Low red blood cells: contact your doctor in case of paleness, shortness of breath on exertion or when resting, persistent tiredness, palpitations, dizziness or headaches. Low white blood cells: contact your doctor in case of temperature > 38°C, chills, sweating, cough,



shortness of breath/pain when breathing, a burning sensation when urinating, diarrhoea accompanied by fever or any other signs suggesting infection. Low platelets: contact your doctor in case of small red dots on your skin, bruising, nosebleeds, bleeding eyes or gums, or blood in your urine or faeces.



Use a soft toothbrush. Do not use rectal thermometers. Do not take aspirin, anti-inflammatories (e.g. Ibuprofen), or herbal products (that can increase bleeding) without medical guidance: consult a healthcare professional. In case of bruising, apply cold (compress or ice pack) or a suitable cream/gel (e.g. arnica) if the skin is not broken.



Tiredness

Eat a balanced diet. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Take care when driving. Rest during the day, while maintaining up to moderate levels of activity. Go to bed at a regular time and get sufficient sleep at night.



Swelling of the face or limbs

Eat a diet low in salt. Avoid tight clothing. If your legs swell, raise your feet when sitting. Wear compression stockings; put them on when getting up in the morning. Weigh yourself regularly. Consult your doctor if this type of swelling occurs.





Only the most common side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask your doctor or pharmacist.

You can also ask your <u>Regional Pharmacovigilance Centre</u> and report any side effects online: signalement-sante-gouv-fr

Remember to go for the lab tests prescribed by your doctor.

Take the medicine prescribed to counteract the side effects, as prescribed.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

Follow the preventive measures.

Contact your doctor rapidly in case of:

- Unusual headaches
- Memory problems, unusual mood swings, confusion
- Vision disorders (blurry or fuzzy vision, sensitivity to light)
- Shortness of breath, very rapid weight gain
- Drowsiness or significant weakness affecting part of your body
- Swelling, redness or pain affecting the hands and/or feet
- Any persistent or worsening side effect

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Note: