

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **AYVAKYT**[®]

Avapritinib tablets

This Patient Medication Information is written for the person who will be taking **AYVAKYT**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **AYVAKYT**. If you have questions or want more information about **AYVAKYT**, or the condition this medication is treating, talk to a healthcare professional.

What **AYVAKYT** is used for:

AYVAKYT is used to treat adults with:

- advanced systemic mastocytosis (AdvSM) which includes:
 - aggressive systemic mastocytosis (ASM),
 - systemic mastocytosis with associated hematological neoplasm (SM-AHN),
 - mast cell leukaemia (MCL)
- indolent systemic mastocytosis (ISM) with symptoms that are not controlled well with certain treatments

How **AYVAKYT** works:

In patients with AdvSM, the overproduced mast cells can build up in different parts of the body, such as liver, bone marrow or spleen. These mast cells also release substances (such as histamine) which can cause various symptoms and damage to involved organs.

AYVAKYT stops the activity of a group of proteins in the body called kinases. It works by targeting a specific change in the gene (mutation) to slow down the growth of mast cells.

The ingredients in **AYVAKYT** are:

Medicinal ingredients: avapritinib

Non-medicinal ingredients:

Copovidone, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide

Blue printing ink (100 mg and 200 mg tablets): ammonium hydroxide 28%, FD&C blue #1/brilliant blue FCF, ferrous ferric oxide/ black iron oxide, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze 45% (20% esterified) in ethanol, titanium dioxide

AYVAKYT comes in the following dosage forms:

- Tablets: 25 mg, 50 mg, 100 mg and 200 mg

Do not use **AYVAKYT** if:

- you are allergic to avapritinib or any other ingredients in this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take AYVAKYT. Talk about any health conditions or problems you may have, including if you:

- have had a bulging and weakening of a blood vessel wall (vascular aneurysm) or bleeding in your brain
- have a history of stroke in the last year.
- have low platelet counts.
- have liver problems.

Other warnings you should know about:

- AYVAKYT may cause:
 - **Bleeding in your brain.** This **may** lead to death. If you have low platelet counts, you may be at a greater risk of bleeding in the brain. For patients with AdvSM, your healthcare professional will check your platelet counts before you start treatment and monitor them as needed during treatment with AYVAKYT. Bleeding in the brain has not been seen in people treated with AYVAKYT for ISM.
 - **Cognitive effects** (problems with thinking and how you remember information). This includes memory loss, changes in memory, or confusion. Contact your healthcare professional if you, your caregiver or family member notices that you are getting forgetful or confused.
 - **Sensitivity to sunlight.** You may become more sensitive to the sun while taking this medicine. It is important to cover sun-exposed areas of skin and use sunscreen with high sun protection factor (SPF).

- **Check-ups and testing**

- While you are taking AYVAKYT, your healthcare professional may ask you to have regular blood tests and weigh you regularly as needed.

- **Children and adolescents (under 18 years of age)**

- You should not take AYVAKYT if you are under 18 years of age. AYVAKYT has not been studied in children and adolescents under 18 years of age.

- **Female patients**

Pregnancy and birth control

- If you are pregnant or planning to become pregnant, there are risks you should discuss with your healthcare professional. This medicine is not recommended for use during pregnancy unless clearly necessary.
- Do NOT become pregnant during treatment with AYVAKYT. It may harm your unborn baby.
- If you are able to become pregnant:
 - Your healthcare professional should check if you are pregnant before you start treatment with this medicine.
 - Use effective method of birth control during treatment and for 6 weeks after completion of treatment. Talk to your healthcare professional about birth control methods that may be right for you
 - Tell your healthcare professional right away if you become pregnant or think you may be pregnant.

Breastfeeding

- Tell your healthcare professional if you are breastfeeding or planning to breastfeed. It is not known if AYVAKYT passes into breast milk.
- Do NOT breastfeed during treatment with this AYVAKYT and for at least 2 weeks following the last dose. Talk to your healthcare professional about the best way to feed your baby during this time.

- **Male patients**

Birth control

- If you have a female partner who are able to become pregnant, use effective method of birth control during treatment and for 2 weeks after completion of treatment. Talk to your healthcare professional about birth control methods that may be right for you.
- Tell your healthcare professional right away if your partner becomes pregnant during treatment with AYVAKYT.

- **Driving and using machines**

- AYVAKYT may affect your ability to concentrate and react. You should avoid or take special care when driving a car or using machines if you experience these side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with AYVAKYT:

- Boceprevir – used to treat hepatitis C
- Atazanavir, cobicistat, efavirenz, etravirine, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir – used to treat HIV infections/AIDS
- Clarithromycin, erythromycin, telithromycin – used to treat bacterial infections
- Itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole – used to treat serious fungal infections
- Conivaptan – used to treat low blood sodium levels (hyponatraemia)
- Rifampicin – used to treat tuberculosis (TB) and some other bacterial infections
- Carbamazepine, phenytoin, fosphenytoin, primidone, phenobarbital – used to treat epilepsy
- St. John's wort (*Hypericum perforatum*) – a herbal medicine used for depression
- Bosentan – used to treat high blood pressure
- Modafinil – used to treat sleep disorders
- Dabrafenib – used to treat certain cancers
- Nafcillin – used to treat certain bacterial infections
- Dexamethasone – used to reduce inflammation
- Alfentanil – used to control pain during operations and medical procedures
- Midazolam – used for anaesthesia, sedation or to decrease anxiety
- Simvastatin – used to treat high cholesterol
- Sirolimus, tacrolimus – used to prevent organ transplant rejection
- Crizotinib – used to treat certain types of cancers
- Dronedarone – used to treat heart rhythm problems
- Imatinib – used to treat certain cancers of the blood and digestive system
- Diltiazem – used to treat high blood pressure and chest pain (angina)

You should not drink grapefruit juice or eat grapefruit while on treatment with AYVAKYT.

How to take AYVAKYT:

- Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Swallow the AYVAKYT tablet(s) whole with a glass of water, on an empty stomach. Do NOT eat for at least 2 hours before and at least 1 hour after taking AYVAKYT.

Usual dose:

Adult dose:

- For patients with AdvSM, the recommended dose is 200 mg by mouth once daily.
- For patients with ISM, the recommended dose is 25 mg by mouth once daily.

If you get side effects, your healthcare professional may change your dose, temporarily stop, or permanently stop treatment. Do not change your dose or stop taking AYVAKYT unless your healthcare professional tells you to.

Overdose:

If you think you, or a person you are caring for, have taken too much AYVAKYT, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844-POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

- If you miss a dose of AYVAKYT, take it as soon as you remember. If your next dose is within 8 hours, skip the missed dose and take the next dose at your regular time.
- Do NOT take two doses within 8 hours to make up for a forgotten dose
- If you vomit after taking a dose of AYVAKYT, do NOT take an extra dose. Take your next dose at your scheduled time.

Possible side effects from using AYVAKYT:

These are not all the possible side effects you may have when taking AYVAKYT. If you experience any side effects not listed here, tell your healthcare professional.

- altered taste
- diarrhea
- nausea, retching and vomiting
- change in hair colour
- tiredness
- headache
- dizziness
- decreased sensation, numbness, tingling, or increased sensitivity to pain in arms and legs
- increased tear production
- nose bleed
- dryness affecting eyes, lips, mouth and skin
- constipation, flatulence (gas)
- abdominal (belly) pain
- rash
- hair loss

- pain in the joint, bone, or muscle
- weight gain
- bruising
- cough
- blurry vision
- swelling: arms, legs, face, eyes, abdominal
- trouble falling asleep (insomnia)
- flushing
- flu and cold symptoms
- weakness
- lower appetite
- bone pain
- anxiety
- shortness of breath
- skin sensitivity to light, skin problems

AYVAKYT may cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects may not occur or occur at lower rates if you are taking AYVAKYT for ISM. Some side effects may be disease **or** dose related.

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Low blood platelets, red blood cells or white blood cells: feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills		X	
Generalized edema: swelling in parts of your body (e.g. arms, legs, feet, ankle, face, eye, joint), weight gain		X	
COMMON			
Ascites (fluid in the abdomen): abdominal pain, feeling of fullness, flat or pushed out navel, increase in weight, shortness of breath		X	
Cardiac failure (heart does not pump blood as well as it should): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or		X	

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
irregular heartbeat, reduced ability to exercise			
Pleural effusion (fluid around the lungs): chest pain, difficult or painful breathing, cough		X	
Signs of bleeding events including in your brain: severe headache, vision problems, severe sleepiness, severe weakness on one side of your body, nausea, vomiting and altered mental status			X
Signs of cognitive effect: memory loss, changes in memory, or confusion		X	
Gastrointestinal hemorrhage (bleeding in the digestive system such as stomach, rectum, or intestine) symptoms include passing blood in the stools or passing black stools, stomach pain, coughing/vomiting up blood		X	
Acute Kidney injury: Blood tests showing decreased kidney function		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store AYVAKYT at room temperature (15°C to 30°C)
- Keep out of reach and sight of children

If you want more information about AYVAKYT:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the Importer and Distributor's website www.medisonpharma.com, or by calling 1-800-696-1341.

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