AYVAKYT® ▼
(avapritinib)

# Dosing and Patient Management Guide

## An educational resource for healthcare professionals treating adult patients with Advanced SM with AYVAKYT® (avapritinib)

AYVAKYT is indicated as a monotherapy for the treatment of adult patients with: aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated haematological neoplasm (SM-AHN) or mast cell leukaemia (MCL), after at least one systemic therapy.[1]

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the Summary of Product Characteristics (SmPC) for how to report adverse reactions.

**Abbreviated Prescribing Information can be found on page 15.**

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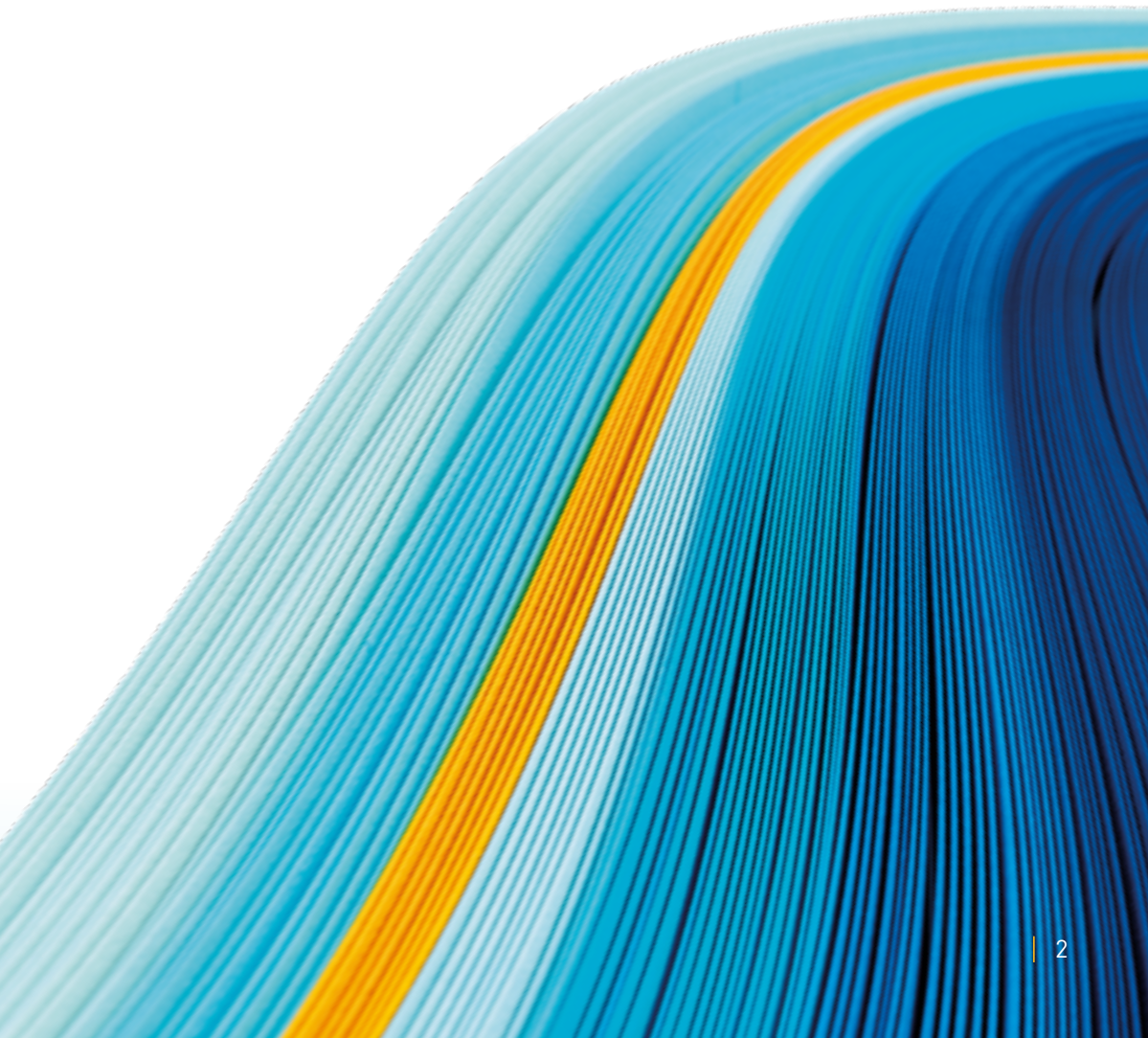
AYVAKYT®
(avapritinib)



# Recommended dosing instructions for your patients on AYVAKYT[1]

**The recommended starting dose for adult patients with Advanced SM is 200 mg.[1]**

**The dose for patients with Advanced SM must not exceed 200 mg once daily.[1]**

## AYVAKYT SHOULD BE TAKEN:

One tablet orally

One time each day

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

Continue treatment until disease progression or unacceptable toxicity occurs. Modify dosage for adverse reactions.[1]

**To initiate treatment with AYVAKYT, patients will need a platelet count of >50 x $10^9$/L.[1]**

Co-administration with strong or moderate CYP3A inhibitors should be avoided because it may increase the plasma concentration of avapritinib.

If concomitant use with a moderate CYP3A inhibitor cannot be avoided, the starting dose of AYVAKYT must be reduced from 200 mg to 50 mg orally once daily.

**Additional instructions:[1]**

- The tablets should be swallowed whole with a glass of water
- Do not make up for a missed dose within 8 hours of the next scheduled dose
- Do not repeat dose if vomiting occurs after taking AYVAKYT but continue with the next scheduled dose

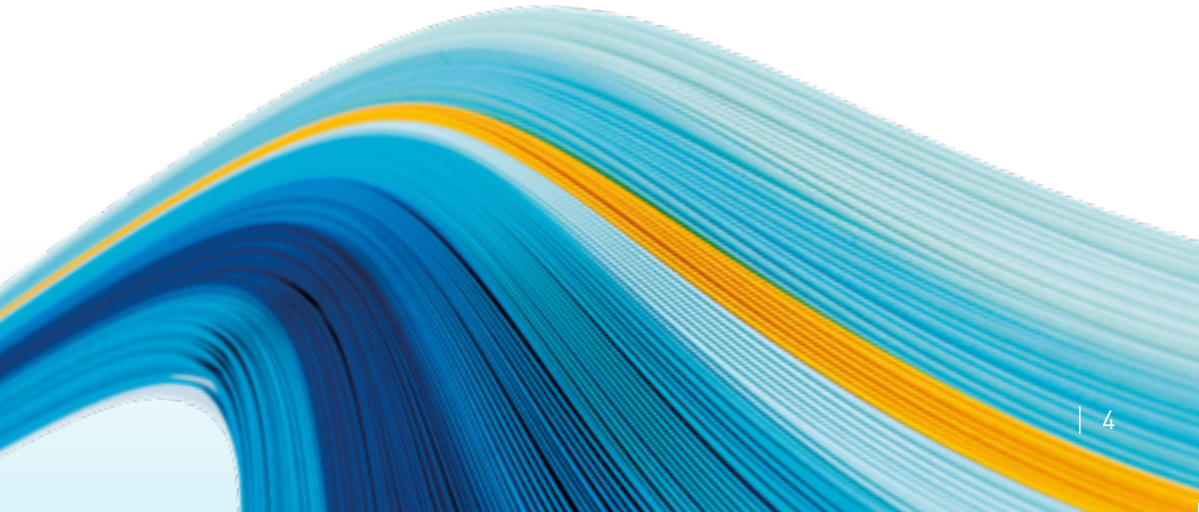
# Advanced SM dose strengths

The recommended starting dose of AYVAKYT for Advanced SM is **200 mg** orally once daily. AYVAKYT is also available in **100 mg, 50 mg**, and **25 mg.**[1]

**AYVAKYT is available in bottles of 30 tablets.**[1]

| Dose Strength | Description[1] |
|---|---|
| 200 mg tablet | Oval, white, film-coated tablet, printed with blue ink. One side reads "BLU" and the other side reads "200" |
| 100 mg tablet | Round, white, film-coated tablet, printed with blue ink. One side reads "BLU" and the other side reads "100" |
| 50 mg tablet | Round, white, film-coated tablet with debossed text. One side reads "BLU" and the other side reads "50" |
| 25 mg tablet | Round, white, film-coated tablet with debossed text. One side reads "BLU" and the other side reads "25" |

**Abbreviated Prescribing Information can be found on page 15.**



# Dose modifications for adverse reactions[1]

Interruption of treatment with or without dose reduction may be considered to manage adverse reactions based on severity and clinical presentation. The dose should be adjusted based on safety and tolerability.[1]

**Recommended dose reductions for adverse reactions[1]**

| Dose Reduction | Starting Dose (200 mg)* |
|---|---|
| First | **100 mg** once daily |
| Second | **50 mg** once daily |
| Third | **25 mg** once daily |

**Recommended dose modifications for patients experiencing specific adverse reactions[1]**

| Adverse Reaction | Severity† | Dosage Modification |
|---|---|---|
| **Intracranial haemorrhage** | All grades | Permanently discontinue AYVAKYT. |
| **Cognitive effects‡** | Grade 1 | Continue at the same dose or reduced dose or interrupt until improvement to baseline or resolution. Resume at the same dose or a reduced dose. |
| | Grade 2 or Grade 3 | Interrupt therapy until improved to baseline, Grade 1, or resolution. Resume at the same dose or at a reduced dose. |
| | Grade 4 | Permanently discontinue AYVAKYT. |
| **Thrombocytopenia** | <50 x $10^9$/L | Interrupt dosing until platelet count is ≥50 x $10^9$/L, then resume at reduced dose as per the recommended reductions. If platelet count does not recover above 50 x $10^9$/L, consider platelet support. |
| **Other** | Grade 3 or Grade 4 | Interrupt therapy until less than or equal to Grade 2. Resume at the same dose or at a reduced dose, if warranted. |

*Permanently discontinue AYVAKYT in patients who are unable to tolerate a dose of 25 mg daily.

† The severity of adverse reactions graded by the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 and 5.0.

‡ Adverse reactions with impact on Activities of Daily Living (ADLs) for Grade 2 or higher adverse reactions.

§See description of the safety profile according to the results from the EXPLORER[2] and PATHFINDER[3] studies in the AYVAKYT SmPC, date of information March 2023.[1]

# AYVAKYT dose modifications in clinical trials[1§]

**EXPLORER & PATHFINDER**

Among Advanced SM patients in clinical trials who started at 200 mg (n=126):

**7.1%**

Permanent discontinuation due to adverse reaction[1]

**PATHFINDER**

Patients with Advanced SM who received at least one prior systemic therapy and a starting dose of 200 mg AYVAKYT (n=47):

**79%**

Dose reduction (median time to reduction, 6 weeks)[1]

Adverse reactions leading to a dose reduction included:[1]

- Thrombocytopenia
- Neutropenia
- Periorbital oedema
- Cognitive disorder
- Oedema peripheral
- Platelet count decreased
- Neutrophil count decreased
- Anaemia
- Asthenia
- Fatigue
- Arthralgia
- Blood alkaline phosphatase increased
- Blood bilirubin increased
- White blood cell count decreased

## RISK OF INTRACRANIAL HAEMORRHAGE

Intracranial haemorrhage occurred in a total (regardless of causality) or 4 (3.2%) of the 126 patients with Advanced SM who received AYVAKYT at a starting dose of 200 mg once daily regardless of platelet count prior to initiation of therapy. The risk of intracranial haemorrhagic events is higher in patients with platelet counts <50 x $10^9$/L. Intracranial haemorrhage occurred in a total (regardless of causality) of 3 (2.5%) of the 121 patients with Advanced SM who received a starting dose of 200 mg once daily and had a platelet count of ≥50 x $10^9$/L prior to initiation of therapy. In 2 of the 3 patients, the event was assessed as related to avapritinib (1.7%). (see Special warnings and precautions for use on page 11).

**Abbreviated Prescribing Information can be found on page 15.**

# Adverse reactions (≥10%) reported in clinical studies in patients with Advanced SM treated with AYVAKYT starting at 200 mg[1*]

| Adverse reactions | All grades % | Grade ≥3 % |
|---|---|---|
| **Blood and lymphatic system disorders** | | |
| Thrombocytopenia[†] | 46.8 | 23.0 |
| Anaemia[†] | 23.0 | 11.9 |
| Neutropenia[†] | 21.4 | 19.0 |
| **General disorders and administration site conditions** | | |
| Oedema[‡] | 69.8 | 4.8 |
| Fatigue[†] | 18.3 | 2.4 |
| **Gastrointestinal disorders** | | |
| Diarrhoea | 14.3 | 1.6 |
| Nausea | 12.7 | - |
| **Nervous system disorders** | | |
| Taste effect[†] | 15.9 | 0.8 |
| Cognitive disorder | 11.9 | 1.6 |
| **Skin and subcutaneous tissue disorders** | | |
| Hair colour changes | 15.1 | - |

*The severity of adverse reactions graded by the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 4.03 and 5.0.

[†]Comprises pooled terms representing similar medical concepts.

[‡]Oedema (including periorbital oedema, oedema peripheral, face oedema, eyelid oedema, fluid retention, generalised oedema, oedema, peripheral swelling, swelling face, eye swelling, conjunctival oedema, laryngeal oedema, localised oedema).

[§]Neuropathy peripheral (including paraesthesia, neuropathy peripheral, hypoaesthesia).

[**]Intracranial haemorrhage (including haemorrhage intracranial, subdural haematoma).

[††]Gastrointestinal haemorrhage (including gastric haemorrhage, gastrointestinal haemorrhage, melaena).

**Abbreviated Prescribing Information can be found on page 15.**

# Adverse reactions occuring in <10% of patients (all grades)[1]

- Leukopenia (8.7%)†
- Vomiting (8.7%)†
- Headache (7.9%)
- Hyperbilirubinaemia (7.9%)†
- Rash (7.9%)†
- Alopecia (7.1%)
- Lacrimation increased (6.3%)
- Weight increased (6.3%)
- Memory impairment (5.6%)†
- Dizziness (5.6%)
- Epistaxis (5.6%)
- Neuropathy peripheral (4.8%)§
- Blood alkaline phosphatase increased (4.8%)
- Transaminases increased (4.8%)†
- Gastroesophageal reflux disease (4.8%)†
- Arthralgia (4.8%)
- Ascites (4.0%)†
- Dryness (4.0%)†
- Constipation (3.2%)
- Abdominal pain (3.2%)†
- Pain (3.2%)
- Contusion (3.2%)
- Intracranial haemorrhage (2.4%)**
- Gastrointestinal haemorrhage (2.4%)††
- Pleural effusion (2.4%)
- Electrocardiogram QT prolonged (1.6%)
- Confusional state (1.6%)
- Pericardial effusion (0.8%)
- Photosensitivity reaction (0.8%)
- Acute kidney injury (0.8%)†

MONITORING

# Patient monitoring

Monitor your patients at initiation and as indicated during treatment to help reduce and manage potential adverse reactions.[1]

## MONITOR YOUR PATIENTS' PLATELET COUNTS[1]

A platelet count must be performed prior to initiation of therapy, every 2 weeks for the first 8 weeks of therapy, and potentially longer depending on what is clinically indicated.

Manage platelet counts of <50 x $10^9$/L by treatment interruption or dose reduction of AYVAKYT. Platelet support may be necessary.

Thrombocytopenia was generally reversible by reducing or interrupting treatment with AYVAKYT.

23% of patients treated with AYVAKYT experienced a Grade ≥3 thrombocytopenia in clinical studies.

| Time on therapy | Monitoring plan | Treatment plan |
|---|---|---|
| **Prior to initiation** | Perform platelet count. | **AYVAKYT is not recommended in Advanced SM patients with platelet counts <50 x $10^9$/L** |
| **First 8 weeks** | Perform platelet count every 2 weeks regardless of baseline platelet count. | If platelet count <50 x $10^9$/L occurs, interrupt AYVAKYT until platelet count is ≥50 x $10^9$/L, then resume at reduced dose.<br><br>If platelet count does not recover above 50 x $10^9$/L, consider platelet support. |
| **After 8 weeks** | Monitor platelet counts:<br>• Every 2 weeks if values are <75 x $10^9$/L (or more frequently as clinically indicated)<br>• Every 4 weeks if values are 75–100 x $10^9$/L<br>• As clinically indicated if values are >100 x $10^9$/L | |

# Monitor for cognitive effects[1]

It is recommended that patients are clinically monitored for signs and symptoms of cognitive events such as new or increased forgetfulness, confusion, and/or difficulty with cognitive functioning. You can help them by ensuring that both patients and caregivers understand the risk of cognitive effects and how they can present.[1]

## ESTABLISH A BASELINE

Work with your patients and their caregivers to establish a cognitive baseline, and set a schedule for periodic monitoring. Patients may experience some cognitive impairment such as brain fog at baseline.[4]

## ENSURE UNDERSTANDING OF COGNITIVE EFFECTS

Explain that they should be monitoring for changes in the following: memory loss, forgetfulness, confusion, and/or difficulty with cognitive functioning.[1]

## EXAMPLES FOR CAREGIVERS

Caregivers will be there to observe your patients when you are not—they may be your best resource for effective patient monitoring. Help your patients' caregivers create a list of activities to monitor, such as:[1]

- Finding their way to familiar places (eg, work, store, friend's house)
- Remembering where they put commonly used items (eg, phone, keys, wallet)
- Speaking or thinking clearly

Patients must notify their healthcare professional immediately if they experience new or worsening cognitive symptoms, so that it can be determined if dose reduction or interruption is clinically appropriate.[1]

For patients with observed cognitive effects related to treatment with AYVAKYT, the recommended dose modification as shown on page 5 must be followed.[1]

Following dose interruption and/or reduction, cognitive effects are generally reversible.[1]

# Special warnings and precautions for use[1]

## HAEMORRHAGES

AYVAKYT has been associated with an increased incidence of haemorrhagic adverse reactions, including serious and severe adverse reactions, like gastrointestinal haemorrhage and intracranial haemorrhage in patients with Advanced SM (see section 4.8 of the SmPC).

Routine surveillance of haemorrhagic adverse reactions must include physical examination. Complete blood counts, including platelets, and coagulation parameters must be monitored, particularly in patients with conditions predisposing to bleeding, and in those treated with anticoagulants (e.g. warfarin and phenprocoumon) or other concomitant medicinal products that increase the risk of bleeding.

## INTRACRANIAL HAEMORRHAGES

Adverse reactions of intracranial haemorrhage occurred in patients who received AYVAKYT. Before initiating AYVAKYT the risk for intracranial haemorrhage should be carefully considered in patients with potential increased risk including those with thrombocytopenia, vascular aneurysm or a history of intracranial haemorrhage or cerebrovascular accident within the prior year.

Patients who experience clinically relevant neurological signs and symptoms (e.g. severe headache, vision problems, somnolence, and/or focal weakness) during treatment with AYVAKYT must interrupt dosing of AYVAKYT and inform their healthcare professional immediately. Brain imaging by magnetic resonance imaging (MRI) or computed tomography (CT) may be performed at the discretion of the physician based on severity and the clinical presentation.

For patients with observed intracranial haemorrhage during treatment with AYVAKYT, regardless of severity grade, AYVAKYT must be permanently discontinued (see section 4.2 of the SmPC).

Serious adverse reactions of intracranial haemorrhage were reported in patients with Advanced SM receiving AYVAKYT (see section 4.8 of the SmPC). The exact mechanism is unknown. The incidence of intracranial haemorrhage was higher in patients with platelet counts <50 x $10^9$/L and in patients with a starting dose of ≥300 mg.

Considering the above, a platelet count must be performed prior to initiating therapy. AYVAKYT is not recommended in patients with platelet counts <50 x $10^9$/L. Following treatment initiation, platelet counts must be performed every 2

**Please see the SmPC for additional information on dosing and administration of AYVAKYT.**

weeks for the first 8 weeks regardless of baseline platelet count. After 8 weeks of treatment, monitor platelet counts every 2 weeks (or more frequently as clinically indicated) if values are less than 75 x $10^9$/L, every 4 weeks if values are between 75 and 100 x $10^9$/L, and as clinically indicated if values are greater than 100 x $10^9$/L.

Manage platelet counts of <50 x $10^9$/L by temporarily interrupting AYVAKYT. Platelet support may be necessary, and the recommended dose modification in Table 2 must be followed (see section 4.2 of the SmPC). Thrombocytopenia was generally reversible by reducing or interrupting AYVAKYT in clinical studies. The maximum dose for patients with AYVAKYT must not exceed 200 mg once daily.

## COGNITIVE EFFECTS

Cognitive effects, such as memory impairment, cognitive disorder, confusional state and encephalopathy, can occur in patients receiving AYVAKYT (see section 4.8 of the SmPC). The mechanism of the cognitive effects is not known.

It is recommended that patients are clinically monitored for signs and symptoms of cognitive events such as new or increased forgetfulness, confusion and/or difficulty with cognitive functioning. Patients must notify their healthcare professional immediately if they experience new or worsening cognitive symptoms.

For patients with observed cognitive effects related to treatment with AYVAKYT, the recommended dose modification in Table 2 must be followed (see section 4.2 of the SmPC). In clinical studies, dose reductions or interruptions improved Grade ≥2 cognitive effects compared to no action.

## FLUID RETENTION

In patients with Advanced SM, localised (facial, periorbital, peripheral, pulmonary oedema, pericardial and/or pleural effusion) or generalised oedema, and ascites have been observed with a frequency category of at least common (see section 4.8 of the SmPC). Other localised oedemas (laryngeal oedema) have been reported uncommonly.

Therefore, it is recommended that patients be evaluated for these adverse reactions including regular assessment of weight and respiratory symptoms. An unexpected rapid weight gain or respiratory symptoms indicating fluid retention must be carefully investigated and appropriate supportive care and therapeutic measures, such as diuretics, should be undertaken. For patients presenting with ascites, it is recommended to evaluate the aetiology of ascites.

# Special warnings and precautions for use[1] (cont.)

## QT INTERVAL PROLONGATION

Prolongation of QT interval has been observed in patients with Advanced SM treated with AYVAKYT in clinical studies. QT interval prolongation may induce an increased risk of ventricular arrhythmias, including Torsade de pointes.

AYVAKYT should be used with caution in patients with known QT interval prolongation or at risk of QT interval prolongation (e.g. due to concomitant medicinal products, pre-existing cardiac disease and/or electrolyte disturbances). Concomitant administration with strong or moderate CYP3A4 inhibitors should be avoided due to the increased risk of adverse reactions, including QT prolongation and related arrhythmias (see section 4.5 of the SmPC). If concomitant use of moderate CYP3A4 inhibitors cannot be avoided, see section 4.2 of the SmPC for dose modification instructions.

Interval assessments of QT by electrocardiogram (ECG) should be considered if AYVAKYT is taken concurrently with medicinal products that can prolong QT interval.

## GASTROINTESTINAL DISORDERS

Diarrhoea, nausea and vomiting were the most commonly reported gastrointestinal adverse reactions in patients with Advanced SM (see section 4.8 of the SmPC). Patients who present with diarrhoea, nausea and vomiting should be evaluated to exclude disease-related aetiologies. Supportive care for gastrointestinal adverse reactions requiring treatment may include medicinal products with antiemetic, antidiarrheal or antacid properties.

The hydration status of patients experiencing gastrointestinal adverse reactions must be closely monitored and treated as per standard clinical practice.

## LABORATORY TESTS

Treatment with AYVAKYT in patients with Advanced SM is associated with anaemia, neutropenia and/or thrombocytopenia. Complete blood counts must be performed on a regular basis during the treatment with AYVAKYT. See also intracranial haemorrhages above in this section and in section 4.8 of the SmPC.

Treatment with AYVAKYT is associated in patients with Advanced SM with elevations in bilirubin and liver transaminases (see section 4.8 of the SmPC). Liver function (transaminases and bilirubin) should be monitored regularly in patients receiving AYVAKYT.

## CYP3A4 INHIBITORS AND INDUCERS

Co-administration with strong or moderate CYP3A inhibitors should be avoided because it may increase the plasma concentration of AYVAKYT (see sections 4.2 and 4.5 of the SmPC).

Co-administration with strong or moderate CYP3A inducers should be avoided because it may decrease the plasma concentrations of AYVAKYT (see section 4.5 of the SmPC).

## PHOTOSENSITIVITY REACTION

Exposure to direct sunlight must be avoided or minimised due to the risk of phototoxicity associated with AYVAKYT. Patients must be instructed to use measures such as protective clothing and sunscreen with high sun protection factor (SPF).

## SODIUM

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

# Abbreviated Prescribing Information (EN)

**AYVAKYT 25 mg film-coated tablets**
**AYVAKYT 50 mg film-coated tablets**
**AYVAKYT 100 mg film-coated tablets**
**AYVAKYT 200 mg film-coated tablets**
**AYVAKYT 300 mg film-coated tablets**
**Active substance:** avapritinib

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the Summary of Product Characteristics (SmPC) for how to report adverse reactions.
**Qualitative and quantitative composition:**
AYVAKYT 25 mg film-coated tablets
Each film-coated tablet contains 25 mg of avapritinib.
AYVAKYT 50 mg film-coated tablets
Each film-coated tablet contains 50 mg of avapritinib.
AYVAKYT 100 mg film-coated tablets
Each film-coated tablet contains 100 mg of avapritinib.
AYVAKYT 200 mg film-coated tablets
Each film-coated tablet contains 200 mg of avapritinib.
AYVAKYT 300 mg film-coated tablets
Each film-coated tablet contains 300 mg of avapritinib.
**List of excipients:**
Tablet core: microcrystalline cellulose, copovidone, croscarmellose sodium, magnesium stearate; tablet coat: talc, macrogol 3350, poly(vinyl alcohol), titanium dioxide (E171); printing ink (only 100 mg, 200 mg and 300 mg film-coated tablets): shellac glaze 45% (20% esterified) in ethanol, brilliant blue FCF (E133), titanium dioxide (E171), black iron oxide (E172), propylene glycol.
**Therapeutic indications:**
Unresectable or metastatic gastrointestinal stromal tumour (GIST)
AYVAKYT is indicated as monotherapy for the treatment of adult patients with unresectable or metastatic gastrointestinal stromal tumours (GIST) harbouring the platelet-derived growth factor receptor alpha (PDGFRA) D842V mutation.
Advanced systemic mastocytosis (AdvSM)
AYVAKYT is indicated as monotherapy for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated haematological neoplasm (SM-AHN) or mast cell leukaemia (MCL), after at least one systemic therapy.
**Contraindications:** Hypersensitivity to the active substance or to any of the excipients.
**Undesirable effects:**
Unresectable or metastatic GIST: *very common (≥ 1/10)*: anaemia, white blood cell count decreased, neutrophil count decreased, decreased appetite, memory impairment, cognitive disorder, dizziness, taste effect, lacrimation increased, abdominal pain, vomiting, diarrhoea, nausea, dryness, gastroesophageal reflux disease, hyperbilirubinaemia, hair colour changes, rash, oedema, fatigue, transaminases increased; common *(≥ 1/100, < 1/10)*: conjunctivitis, thrombocytopenia, lymphocyte count decreased, hypophosphataemia, hypokalaemia, hypomagnesaemia, hyponatraemia, dehydration, hypoalbuminaemia, hypocalcaemia, confusional state, depression, anxiety, insomnia, intracranial haemorrhage, mental impairment, neuropathy peripheral, somnolence, aphasia, hypokinesia, headache, balance disorder, speech disorder, tremor, ocular haemorrhage, vision blurred, conjunctival haemorrhage, photophobia, vertigo, hypertension, pleural effusion, dyspnoea, nasal congestion, cough, gastrointestinal haemorrhage, ascites, constipation, dysphagia, stomatitis, flatulence, salivary hypersecretion, palmar-plantar erythrodysaesthesia syndrome, photosensitivity reaction, skin hypopigmentation, pruritus, alopecia, myalgia, arthralgia, back pain, muscle spasms, acute kidney injury, blood creatinine increased, haematuria, asthenia, pyrexia, malaise, feeling cold, electrocardiogram QT prolonged, blood creatine phosphokinase increased, weight decreased, weight increased, blood lactate dehydrogenase increased; *uncommon (≥ 1/1.000, < 1/100)*: tumour haemorrhage, encephalopathy, pericardial effusion, hepatic haemorrhage.
Advanced systemic mastocytosis: *very common (≥ 1/10)*: thrombocytopenia, anaemia, neutropenia, taste effect, cognitive disorder, diarrhoea, nausea, hair colour changes, oedema, fatigue; *common (≥ 1/100, < 1/10)*: leukopenia, confusional state, headache, memory impairment, dizziness, neuropathy peripheral, intracranial haemorrhage, lacrimation increased, epistaxis, pleural effusion, vomiting, gastroesophageal reflux disease, ascites, dryness, constipation, abdominal pain, gastrointestinal haemorrhage, hyperbilirubinaemia, rash, alopecia, arthralgia, pain, weight increased, blood alkaline phosphatase increased, transaminase increased, electrocardiogram QT prolonged, contusion; uncommon *(≥ 1/1.000, < 1/100)*: pericardial effusion, photosensitivity reaction, acute kidney injury.
**General classification for supply:** Germany: medicinal product subject to medical prescription. Austria: available only on prescription and only in pharmacies, repeated dispensation prohibited.
**Pharmacotherapeutic group:** antineoplastic agents, protein kinase inhibitor, ATC code: L01EX18.
**Pharmaceutical entrepreneur/Marketing authorisation holder:** Blueprint Medicines (Netherlands) B.V., Gustav Mahlerplein 2, 1082 MA Amsterdam, Netherlands.
**Further information:** For detailed information on warnings and precautions for use, interactions, pregnancy and lactation as well as undesirable effects, please refer to the published Summary of Product Characteristics. **Status:** March 2022

# Notes

# Notes

# Managing your patients with Advanced SM taking AYVAKYT

## INITIATE[1]

The recommended starting dose of AYVAKYT is 200 mg, one tablet orally, once daily on an empty stomach. The maximum dose for patients with Advanced SM should not exceed 200 mg once daily. AYVAKYT is also available in 100 mg, 50 mg, and 25 mg dose strengths for dose modifications due to adverse events or drug interactions.

A platelet count must be performed prior to initiating therapy. To initiate treatment with AYVAKYT, patients will need a platelet count of >50 x $10^9$/L.

## MONITOR[1]

Observe your patients for signs of adverse reactions and inform them of the potential side effects. The signs you identify or information they share can help you decide whether dose modifications may be appropriate.

Platelet counts should be monitored throughout AYVAKYT treatment. See the detailed monitoring guidelines within this guide and the AYVAKYT SmPC.

## MODIFY[1]

Modifying dosage for your individual patients to manage adverse reactions may be necessary. See the detailed dose modification information within this guide and the AYVAKYT SmPC.


**References:**

**1.** AYVAKYT® (avapritinib). Summary of Product Characteristics; March 2023. Available at: https://www.ema.europa.eu/en/documents/product-information/ayvakyt-epar-product-information_en.pdf.
**2.** DeAngelo DJ, *et al. Nat Med.* 2021;27(12):2183–2191.
**3.** Gotlib J, *et al. Nat Med.* 2021;27(12):2192–2199.
**4.** Jennings SV, *et al. Immunol Allergy Clin North Am.* 2018;38(3):505–525.


blueprint™ MEDICINES

AYVAKYT® (avapritinib)



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