CAMZYOS®▼ (mavacamten)

Healthcare Professional Checklist

▼ CAMZYOS is subject to additional monitoring to quickly identify new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Local Approval Number: 3500-ELR-2500001

HEALTHCARE PROFESSIONAL CHECKLIST

The checklist below includes information to consider when treating patients receiving CAMZYOS and counselling patients and/or their caregiver(s), more specifically in regard to the following risks:

- Embryo-foetal toxicity
- Heart failure due to systolic dysfunction
- Adverse events due to overexposure to mavacamten resulting from interaction with CYP (Cytochrome P450) 2C19 inhibitors in ultrarapid and intermediate CYP2C19 metabolizers and moderate or strong CYP3A4 inhibitors in poor and normal CYP2C19 metabolizers

Please note that this checklist is not meant to be all-inclusive.

Prior to starting treatment
For patients of childbearing potential:
☐ Confirm a negative pregnancy test.
☐ Educate on the risk of embryo-foetal toxicity associated with CAMZYOS. Counsel on the need to avoid pregnancy and the need for an effective form of contraception during treatment with CAMZYOS and for 6 months following discontinuation.
☐ Instruct patients to contact you or another member of your healthcare team **immediately** if they become pregnant or suspect they may be pregnant.
For all patients:
☐ Obtain a medical history from the patient to determine risk factors for heart failure.
☐ Complete an echocardiogram to confirm that the patient's left ventricular ejection fraction (LVEF) is ≥55% prior to initiating CAMZYOS.
☐ Patients should be genotyped for CYP2C19 phenotype in order to determine appropriate CAMZYOS dose. If treatment occurs prior to determination of CYP2C19 phenotype, patients should follow dosing instructions for poor metabolisers until CYP2C19 phenotype is determined (see Summary of Product Characteristics Figure 1 and Table 1 in Section 4.2).
☐ Assess for potential interactions involving CAMZYOS and any medicine (including prescription and over-the-counter medicines), herbal supplements and grapefruit juice. Detailed guidance on dose modifications/contraindications with concomitant medicines, based on the patient's CYP2C19 phenotype status, is included in the Summary of Product Characteristics (Table 1 and Table 2 of Section 4).
☐ Inform the patient of the risk of heart failure associated with CAMZYOS and that they must consult their healthcare professional or seek medical attention immediately if they experience worsening, persistent or new shortness of breath, chest pain, fatigue, palpitations or leg swelling.
☐ Counsel the patient on the risks of potential interactions involving CAMZYOS and to not start or stop taking any medications or change the dose of any medication they are taking without talking to you first.

☐ Provide the patient with the **Patient Guide** and highlight the **Patient Card** within the guide.
During treatment at each clinical visit (as described in the Summary of Product Characteristics)
For patients of childbearing potential:
☐ Remind patients of the risk of embryo-foetal toxicity associated with CAMZYOS. Counsel on the need to avoid pregnancy and the need for an effective form of contraception during treatment and for 6 months following discontinuation.
☐ Periodically check pregnancy status throughout treatment.
☐ Instruct patients to contact you or another member of your healthcare team **immediately** if they become pregnant or suspect they may be pregnant.

For all patients:
☐ Confirm LVEF is ≥50% by echocardiogram assessment. If at any visit LVEF is <50%, interrupt treatment for 4 weeks and until LVEF returns to ≥50%.
☐ Assess the left ventricular outflow tract (LVOT) gradient with the Valsalva manouvre and adjust the dose per the guidance provided in the Summary of Product Characteristics Section 4.2.
☐ Assess the patient for signs, symptoms and clinical findings of heart failure per the guidance provided in the Summary of Product Characteristics Sections 4.2 and 4.4.
☐ Assess for intercurrent illnesses such as infections or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia).
☐ Assess for interactions involving CAMZYOS and any medicine (including prescription and over-the-counter medicines), herbal supplements and grapefruit juice that the patient has newly started, has changed the dose of or plans on taking in the future. Detailed guidance on dose modifications/contraindications with concomitant medicines, based on the patient's CYP2C19 phenotype status, is included in the Summary of Product Characteristics (Table 1 and Table 2 of Section 4).
☐ Remind the patient of the risks associated with CAMZYOS and that they must consult their healthcare professional or seek medical attention immediately if they experience worsening, persistent or new shortness of breath, chest pain, fatigue, palpitations or leg swelling.
☐ Counsel the patient on the risks of potential interactions involving CAMZYOS.
☐ Counsel the patient on actions to take in case of an overdose and missed or delayed doses.
☐ Provide the patient with the **Patient Guide** and **Patient Card** if needed.
After treatment
For patients of childbearing potential:
☐ Counsel patients on the need to avoid pregnancy and the need for an effective form of contraception for 6 months following discontinuation of CAMZYOS.

REPORTING ADVERSE EVENTS

The safe use of CAMZYOS is of paramount importance. As part of our ongoing safety monitoring, Bristol Myers Squibb wishes to be informed of adverse events that have occurred during use of CAMZYOS. Please report any adverse events and pregnancies to: pv@ammangion.com or tel 00 356 2397 6333.

Suspected Adverse Drug Reactions (side effects) or medication errors may also be reported using the Medicines Authority ADR reporting form available online at http://www.medicinesauthority.gov.mt/adrportal and sent to the Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to:

postlicensing.medicinesauthority@gov.mt

CONTACT DETAILS

If you have any questions regarding CAMZYOS or require more information, please contact Bristol Myers Squibb.

Telephone: 00 356 2397 6333

Email: pv@ammangion.com

Date of Health Authority Approval: 10 January 2025
Local Approval Number: 3500-ELR-2500001