CAMZYOS®▼ (mavacamten)

Healthcare Professional Checklist

Date of HPRA Approval: Jan 2026
Local Approval Number: 3500-IE-2500002
Date of Preparation: Jan 2026

Bristol Myers Squibb®

▼ 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 via HPRA Pharmacovigilance at www.hpra.ie. Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.

HEALTHCARE PROFESSIONAL CHECKLIST

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

- Embryo-fetal 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 metabolisers and moderate or strong CYP3A4 inhibitors in poor and normal CYP2C19 metabolisers

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-fetal toxicity associated with mavacamten. Counsel on the need to avoid pregnancy and the need for an effective form of contraception during treatment with mavacamten 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:

- ☐ Complete an echocardiogram to confirm that the patient's left ventricular ejection fraction (LVEF) is ≥55% prior to initiating mavacamten.
- ☐ Patients should be genotyped for CYP2C19 phenotype in order to determine the appropriate mavacamten dose.
- ☐ Assess for potential interactions involving mavacamten 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 mavacamten 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 mavacamten 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-fetal toxicity associated with mavacamten. 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 manoeuvre 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 mavacamten 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 mavacamten 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 mavacamten.
- ☐ 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 mavacamten.

REPORTING ADVERSE EVENTS

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

The safe use of mavacamten 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 mavacamten. Please report any adverse events and pregnancies to Bristol Myers Squibb Medical Information on medical.information@bms.com or 1 800 749 749. You should also report adverse events to the HPRA at www.hpra.ie.

CONTACT DETAILS

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

Telephone: 1 800 749 749

Email: medical.information@bms.com

Date of HPRA Approval: Jan 2026
Local Approval Number: 3500-IE-2500002, Jan 2026
3500-GL-2400011 Dec-2024