PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Bristol Myers Squibb®

January 2026

Camzyos® ▼ (mavacamten): Introduction of additional Risk Minimisation Materials (aRMM)

Dear Healthcare Professional,

Bristol-Myers Squibb (BMS) has received marketing authorisation for Camzyos® ▼ (mavacamten) throughout the European Union for the treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients.

Mavacamten is a selective allosteric inhibitor of cardiac myosin that selectively targets cardiac myosin and reversibly inhibits its binding to actin.

As part of BMS's commitment to patient safety and to fulfil the requirements of the marketing authorisation for mavacamten, BMS are introducing educational materials to support Healthcare Professionals and Patients to manage the following important risks of mavacamten:

- Heart failure due to systolic dysfunction
- Adverse events due to overexposure to mavacamten resulting from interaction with CYP2C19 inhibitors in ultrarapid and intermediate CYP2C19 metabolisers and moderate or strong CYP3A4 inhibitors in poor and normal CYP2C19 metabolisers
- Embryo-fetal toxicity

The following educational materials have been developed in agreement with the European Medicines Agency (EMA) and the Health Products Regulatory Authority (HPRA). Please ensure you are familiar with their contents before you prescribe mavacamten.

- **Healthcare Professional Checklist**
  The Checklist will support the communication of critical tasks and actions by the prescriber throughout the patient's cycle of treatment with mavacamten; before starting treatment, during treatment, and after treatment has been discontinued.

- **Patient Guide and Patient Card – to be distributed by the Healthcare Professional**
  These patient educational materials will support the communication of critical safety measures to patients, including notifying their doctor if they experience symptoms of heart failure, not starting or stopping any medications without talking to their doctor, and avoiding pregnancy. Embryo-fetal toxicity risk information is presented as a tear-out in the Patient Guide so that it may be removed for patients where the embryo-fetal risk does not apply.

Enclosed with this letter is a hard copy of the Healthcare Professional Checklist, Patient Guide and Patient Card. We kindly request that you disseminate these materials to other relevant colleagues.

Date of Preparation: Jan 2026
3500-IE-2500005
HPRA Approval: Jan 2026

This is a non-promotional letter intended for Healthcare Professionals in Ireland only.

Bristol-Myers Squibb Pharmaceuticals uc

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Karen Costello
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For full prescribing information, please consult the mavacamten Summary of Product Characteristics (SmPC) which can be found on www.medicines.ie (enter 'Camzyos' or 'mavacamten' in the 'Search' box, click on the required medicine, and then click on the 'SPC' tab) or www.hpra.ie (enter 'Camzyos' or 'mavacamten' in the 'Find a medicine' search box and click on 'EMA' next to any of the medicines that appear. Once the European Medicines Agency (EMA) page for Camzyos opens up, navigate to the 'Product Information' section on this page).

Reporting adverse events

▼ This medicinal product is subject to additional monitoring to 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 events and pregnancies should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Resources

Electronic copies of the mavacamten aRMM are digitally accessible to be readable and navigable by assistive technology users. These can be found on www.medicines.ie (enter 'Camzyos' or 'mavacamten' in the 'Search' box, click on the required medicine, and then click on the 'Ed Material' tabs) or www.hpra.ie (enter 'Camzyos' or 'mavacamten' in the 'Find a medicine' search box and click on 'EdM' next to any of the medicines that appear).

Further hard copies of the aRMM can be ordered by contacting BMS Medical Information (Telephone: 1 800 749 749; E-mail: medical.information@bms.com).

Company Contact Point

Should you have any questions or require further information regarding the use of mavacamten, please contact BMS Medical Information (Telephone: 1 800 749 749; E-mail: medical.information@bms.com).

Yours sincerely,

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