CAMZYOS®▼ (mavacamten)

Patient Guide

▼ CAMZYOS is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may experience.

Local Approval Number: 3500-ELR-2500003

IMPORTANT SAFETY INFORMATION FOR PATIENTS OF CHILDBEARING POTENTIAL

If you are of childbearing potential, please review the information below before you start treatment with CAMZYOS and keep this page for your reference.

CAMZYOS and the risk of embryo-foetal toxicity (toxicity to an unborn baby)

CAMZYOS must not be taken if you are pregnant or if you are of childbearing potential and are not using an effective method of contraception (birth control) as CAMZYOS may cause harm to an unborn baby.

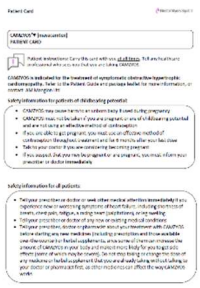
If you are able to get pregnant, you will need a confirmed negative pregnancy test before you start taking CAMZYOS. You must use an effective method of contraception throughout treatment and for 6 months after your last dose of CAMZYOS. You should discuss with your doctor which method(s) of contraception is/are the most suitable for you.

Talk to your doctor if you are considering becoming pregnant. If you suspect you may be pregnant or are pregnant while receiving CAMZYOS, tell your prescriber or doctor **immediately**. Your prescriber or doctor will discuss your treatment options with you.

This **Patient Guide** contains a **Patient Card.**

Carry this Patient Card with you at all times.

Tell any healthcare professional who sees you that you are taking CAMZYOS. The **Patient Card** contains information on the main risks of CAMZYOS and contact details of your prescriber.



Please ensure that you read the package leaflet for this medicine, which gives more information about CAMZYOS. If you have any further questions, talk to your prescriber, doctor or pharmacist.

WHAT ARE ECHOCARDIOGRAMS, AND WHY ARE THEY IMPORTANT?

Regular echocardiograms (also known as echos) will help your doctor evaluate how CAMZYOS affects your heart. An echo is a test that uses sound waves to create pictures of the heart. These tests allow your doctor to see how your heart is responding to treatment and make sure you are on the optimal dose. Based on the echo results, your doctor may increase, decrease or maintain your dose of CAMZYOS or pause or stop your treatment. Your first echo will be performed before starting CAMZYOS. Follow-up echos will be 4, 8 and 12 weeks after your first dose of CAMZYOS and then every 12 weeks afterwards until an individual maintenance dose has been achieved. After that, echo assessment should be done every 6 months.

You will also need to have echos as instructed by your doctor if your dose of CAMZYOS is changed or if the dose of another medicine you are taking is changed.

It is important to schedule and attend echos as instructed by your prescriber. Set reminders on your phone or calendar to help you remember the date and time of your echos.

IMPORTANT SAFETY INFORMATION

There are three main risks associated with treatment with CAMZYOS:

- Embryo-foetal toxicity (toxicity to an unborn baby) (please see page 2)
- Heart failure due to systolic dysfunction, a condition where the heart cannot pump enough blood to the body
- Increase in the amount of mavacamten in the body due to interactions with certain medicines and herbal supplements, which can make patients more likely to get side effects (some of which may be severe)

Other possible side effects related to CAMZYOS are outlined in the package leaflet.

CAMZYOS and heart failure

Heart failure due to systolic dysfunction is a serious and sometimes fatal condition.

Tell your prescriber or doctor, or seek other medical attention **immediately** if you experience new or worsening symptoms of heart failure, including shortness of breath, chest pain, fatigue, a racing heart (palpitations), or leg swelling.

Tell your prescriber or doctor of any new or existing medical condition(s) you experience before and during treatment with CAMZYOS.

CAMZYOS and interactions

Some medicines, including those available over-the-counter, and some herbal supplements can affect the amount of CAMZYOS in your body and make it more likely for you to get side effects (some of which may be severe). Tell your prescriber, doctor or pharmacist about all the prescription medicines, over-the-counter medicines and herbal supplements you take, even if you do not take them every day. **Do not** start taking, stop taking or change the dose of any of your medicines or herbal supplements without talking to your prescriber, doctor or pharmacist.

Some examples of products that may affect how much CAMZYOS is in your body are shown in **Table 1**. Please note, these examples are a guide and are not considered a comprehensive list of all possible medicines that may fit this category. Intermittent use of products that might affect the levels of CAMZYOS in your body, including prescription and over-the-counter medicines, vitamins, herbal supplements and grapefruit juice, is not recommended.

Table 1: Examples of products that may affect CAMZYOS

Products	Condition treated
Omeprazole, esomeprazole	Gastric ulcers and acid reflux
Clarithromycin, rifampicin	Bacterial infections
Verapamil, diltiazem	Heart conditions
Fluconazole, itraconazole, ketoconazole, posaconazole, voriconazole	Fungal infections
Fluoxetine, fluvoxamine	Depression
Ritonavir, cobicistat	Human immunodeficiency virus (HIV)
Grapefruit juice	

WHEN SHOULD I SEEK MEDICAL ATTENTION?

Tell any healthcare professional who sees you if any side effects occur while taking CAMZYOS, even those not discussed in this **Patient Guide**. Possible side effects and details of how to report them are also provided in the package leaflet. Reporting side effects to the Medicines Authority helps collect additional safety information on this medicine.

Suspected Adverse Drug Reactions (side effects) or medication errors may 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

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: AM Mangion Ltd on Tel No 00356 23976333 and email pv@ammangion.com

Tell your prescriber or doctor, or seek other medical attention **immediately** if you experience new or worsening symptoms of heart failure, including shortness of breath, chest pain, fatigue, a racing heart (palpitations), or leg swelling.

FURTHER INFORMATION

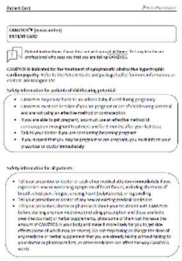
Date of Health Authority Approval: 10 January 2025
Local Approval Number: 3500-ELR-2500003

If you have any questions or concerns regarding CAMZYOS, please discuss them with your prescriber, doctor, pharmacist or any member of your healthcare team.

For further information, please contact: AM Mangion Ltd:

Telephone: 00 356 23976333

Email: pv@ammangion.com



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