

CAMZYOS® ▼ (mavacamten)

Patient Guide

“Risks associated with the use of the product.”

“This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.”



▼ 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.

INTRODUCTION

You have been provided with this **Patient Guide** because you have been prescribed CAMZYOS. CAMZYOS is a prescription-only heart medicine used to treat adults with symptomatic hypertrophic cardiomyopathy also known as (obstructive hypertrophic cardiomyopathy oHCM).



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 patient information leaflet for this medicine, which gives more information about CAMZYOS.

If you have any further questions, talk to your prescriber, doctor or pharmacist.



WHAT IS SYMPTOMATIC OBSTRUCTIVE (HYPERTROPHIC CARDIOMYOPATHY HCM)?

Hypertrophic cardiomyopathy, or HCM, causes the heart muscle wall to thicken and stiffen, making it harder for the heart to fill with blood. In some patients with HCM, the heart muscle becomes so thick that it blocks or reduces blood flow from the heart to the rest of the body.

HOW DOES CAMZYOS WORK?

CAMZYOS works by reducing excessive contraction of the heart and the obstruction of blood flow to the body. As a result, it may improve your symptoms and your ability to exercise.

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.

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:

- Heart failure due to systolic dysfunction, a condition where the heart cannot pump enough blood to the body
- Heart failure due to interactions with certain medicines and herbal supplements
- Embryo-foetal toxicity (toxicity to an unborn baby)

Other possible side effects related to CAMZYOS are outlined in the patient information 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. Certain conditions, such as infections or atrial fibrillation (irregular and rapid heartbeat), may impact your treatment with CAMZYOS.



IMPORTANT SAFETY INFORMATION (continued)

CAMZYOS and drug interactions

Some medicines, including those available over-the-counter, and some herbal supplements can affect the levels of CAMZYOS in your body and may increase the risk of heart failure due to systolic dysfunction. 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 medicines and 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, herbal supplements and grapefruit juice, is not recommended.

Table 1: Examples of medicines and products that may affect CAMZYOS

Medicines/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)
Telaprevir	Hepatitis C
Grapefruit juice	



IMPORTANT SAFETY INFORMATION (continued)

CAMZYOS and embryo-foetal toxicity (toxicity to unborn baby)

CAMZYOS must not be taken if you are pregnant or if you are of child-bearing 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.



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 patient information leaflet. Reporting side effects to the *Saudi Food and Drug Authority (SFDA)* helps collect additional safety information on this medicine.

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

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

Patient Alert Card
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For reporting any suspected adverse reactions via the national reporting system :



Bristol Myers Squibb™

Bristol Myers Squibb International Corporation,
Saudi Arabia:

At: medinfo.saudiarabia@bms.com

or call: 800 844 7710

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA):

SFDA call center: 19999

E-mail: npc.drug@sfd.gov.sa

Website: <http://ade.sfda.gov.sa>