

CAMZYOS[®] (mavacamten)

Patient Guide



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 New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (also known as HCM) with mild to significant symptoms during daily activity to improve symptoms and functional capacity.

CAMZYOS® (mavacamten)
PATIENT CARD

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 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 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. This will mean that you will have a follow-up echo 4 and 8 weeks after your dose is changed and then return to the regular echo schedule of every 12 weeks.



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-fetal toxicity (toxicity to an unborn baby).

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

CAMZYOS and heart failure

Heart failure due to systolic dysfunction is a serious medical condition that sometimes can lead to death.

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, swelling in your legs, a racing sensation in your heart (palpitations), or rapid weight gain.

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, vitamins or herbal supplements without consulting 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, vitamins, 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 cimetidine | 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 | |



IMPORTANT SAFETY INFORMATION (CONTINUED)

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

If you are pregnant or plan to become pregnant, consult your doctor before starting treatment with CAMZYOS. CAMZYOS may harm your unborn baby.

If you are able to get pregnant, you will need a confirmed negative pregnancy test before you start taking CAMZYOS. You should use an effective method of contraception throughout treatment with CAMZYOS and for 4 months after your last dose of CAMZYOS. CAMZYOS may reduce how well hormonal birth control works. 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 leaflet.

Reporting side effects to the Israeli Ministry of Health helps collect additional safety information on this medicine.

You may report side effects to the Israeli Ministry of Health by using the on-line form for reporting adverse events on the Home page of the Ministry of health website: www.health.gov.il or by entering the following link: <https://sideeffects.health.gov.il>

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, swelling in your legs, a racing sensation in your heart (palpitations) or rapid weight gain.



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.

For further information or to report side effects, please contact BMS at:

Telephone: 1809-388054 (A Toll-free number)

Email: medinfo.Israel@bms.com

To obtain additional copies of this Patient Guide (and the Patient Card included herein), please contact BMS Israel by phone 03-5231021, or by fax 03-9226896.







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