

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **CAMZYOS**[®]

mavacamten capsules

Read this carefully before you start taking **CAMZYOS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CAMZYOS**.

Serious warnings and precautions box

CAMZYOS may cause serious side effects, including:

- **Heart failure** (a condition where the heart cannot pump blood with enough force): It is a serious condition that can lead to death. You must have echocardiograms before you take your first dose and regularly during your treatment with CAMZYOS. This is to help your healthcare professional understand how your heart is responding to CAMZYOS. People who develop a serious infection or irregular heartbeat or who are having major heart surgery may be at a greater risk of heart failure during treatment with CAMZYOS. Tell your healthcare professional **right away** if you develop new or worsening:
 - shortness of breath;
 - swelling in your legs;
 - chest pain;
 - a racing sensation in your heart (palpitations);
 - fatigue;
 - rapid weight gain.
- **The risk of heart failure is also increased when CAMZYOS is taken with certain other medicines.** Tell your healthcare professional about all of the medicines you take before and during your treatment with CAMZYOS. These include prescribed medications and those obtained over-the-counter. Your healthcare professional will tell you if you can take them during your treatment with CAMZYOS.
- **Because of the serious risk of heart failure,** your healthcare professional will make sure you understand how to take CAMZYOS safely before you start your treatment. This includes returning for echocardiograms when advised by your healthcare professional.

See the **Serious side effects and what to do about them** table for more information on this and other serious side effects.

What is CAMZYOS used for?

CAMZYOS is used to treat obstructive hypertrophic cardiomyopathy (oHCM) in adults with symptoms of the disorder.

oHCM is a disorder in which the heart muscle contracts too much and becomes abnormally thick. It usually affects the septum, which is the wall between the two lower chambers of the heart (ventricles).

The thickened heart muscle can become stiff and prevent the heart from adequately pumping blood to the rest of the body.

How does CAMZYOS work:

CAMZYOS belongs to a group of medicines called cardiac myosin inhibitors. It works by relaxing the muscles in your heart, which improves your heart's ability to pump blood to the rest of your body. This may improve your symptoms and your ability to be active.

The ingredients in CAMZYOS are:

Medicinal ingredient: Mavacamten

Non-medicinal ingredients: [List all non-medicinal ingredients in alphabetical order]

Non-medicinal ingredients: Croscarmellose sodium, hypromellose, magnesium stearate (non-bovine), mannitol, and silicon dioxide.

Capsule shell 2.5 mg: black iron oxide, gelatin (bovine and/ or porcine), red iron oxide, titanium dioxide.

Capsule shell 5 mg: gelatin (bovine and/ or porcine), titanium dioxide, yellow iron oxide.

Capsule shell 10 mg: gelatin (bovine and/ or porcine), red iron oxide, titanium dioxide.

Capsule shell 15 mg: black iron oxide, gelatin (bovine and/ or porcine), titanium dioxide.

Imprinting Ink: black iron oxide, potassium hydroxide, propylene glycol, shellac, strong ammonia solution.

CAMZYOS comes in the following dosage forms:

Capsules: 2.5 mg, 5 mg, 10 mg and 15 mg.

Do not use CAMZYOS if:

- you are allergic to mavacamten or any of the other ingredients in CAMZYOS.
- you are taking medicines that are:
 - strong cytochrome P450 (CYP) enzyme 2C19 inhibitors.
 - moderate and strong CYP 2C19 or CYP 3A4 inducers.Ask your healthcare professional if you are unsure.
- you are pregnant, planning to become pregnant, or think you might be pregnant.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CAMZYOS. Talk about any health conditions or problems you may have, including if you:

- are taking any prescription and over-the-counter medicines, vitamins, herbal supplements and grapefruit juice. Especially tell your healthcare professional if you take:
 - medicines used to treat excess stomach acid (e.g., omeprazole or esomeprazole)
 - medicines used to treat high blood pressure (e.g., beta blockers, verapamil, diltiazem).
 - disopyramide (used to treat an irregular heart beat).
 - ranolazine (used to treat chest pain)
- have an irregular heart beat (arrhythmia).
- currently suffer from another serious illness (e.g., serious infection).
- have severe liver or kidney problems.
- are able to become pregnant.
- are breastfeeding or planning to breastfeed.

Other warnings you should know about:

Contraception (for female patients): If you are female and are able to become pregnant:

- your healthcare professional will ask you to take a pregnancy test to confirm that you are not pregnant before you start your treatment with CAMZYOS;
- you should use an effective birth control method (contraception) during your treatment with CAMZYOS and for up to 4 months after your last dose of CAMZYOS.

Pregnancy: Do not take CAMZYOS during pregnancy. CAMZYOS may harm your unborn baby. Your healthcare professional will discuss the potential risks with you. If you discover that you are pregnant while taking CAMZYOS, stop taking this medicine and tell your healthcare professional **right away**.

Breast-feeding: It is not known if CAMZYOS can pass into breast milk and harm your baby. You and your healthcare professional will decide whether you should take CAMZYOS or breastfeed. You should not do both at the same time. If the decision is to take CAMZYOS, you should not breastfeed during treatment with CAMZYOS and for up to 4 months after the last dose of CAMZYOS.

Driving or using machines: CAMZYOS may make you feel dizzy. Avoid driving, using machinery, or doing activities that require you to be alert if you feel dizzy.

Monitoring and Laboratory Tests: You will have regular visits with your healthcare professional and they will monitor and assess your heart closely while you are taking CAMZYOS.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions:

Do not take CAMZYOS with medicines that are:

- Strong CYP 2C19 inhibitors (e.g., ticlopidine);
- moderate and strong CYP 2C19 or CYP 3A4 inducers (e.g., rifampicin, carbamazepine, St. John's Wort).

- Ask your healthcare professional if you are unsure you are taking any of these types of medicines.

The following may interact with CAMZYOS:

- medicines used to treat excess stomach acid (e.g., omeprazole or esomeprazole)
- disopyramide (used to treat an irregular heart beat)
- ranolazine (used to treat chest pain)
- midazolam (used to produce sleepiness and relieve anxiety before surgery)

Do not stop or change the dose of a medicine or start a new medicine without telling your healthcare professional. This is because some medicines can affect the way CAMZYOS works. Some medicines can increase the levels of CAMZYOS in your body and make it more likely for you to get side effects that are possibly severe. Some medicines can reduce the levels of CAMZYOS in your body and may reduce its beneficial effects.

Know the medicines you take. Keep an updated list of them to show or tell your healthcare professional and pharmacist when you get a new medicine.

How to take CAMZYOS:

- Take CAMZYOS exactly as your healthcare professional has told you to take it.
- Take CAMZYOS once a day, with or without food.
- Swallow the capsule whole with water. Do not break, open, or chew the capsule.
- Do not change your dose of CAMZYOS without talking to your healthcare professional first.
- Your healthcare professional may change your dose, temporarily stop, or permanently stop your treatment with CAMZYOS if you have certain side effects. Tell your healthcare professional **right away** if you are experiencing any side effects during your treatment.

Usual dose:

- Your healthcare professional will decide on the dose that is right for you. The dose of CAMZYOS prescribed to you will depend on your heart function. Your healthcare professional will assess your heart function before you take CAMZYOS and regularly during treatment and adjust your dose during treatment if needed.
- The recommended starting dose is 5 mg once a day.

Overdose:

Symptoms of an overdose with CAMZYOS may include:

- fainting;
- low blood pressure, which may make you feel dizzy or light-headed;
- heart unable to pump enough blood to the rest of the body (heart failure);

- heart suddenly stops beating (cardiac arrest).

If you think you, or a person you are caring for, have taken too much CAMZYOS, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose, take it as soon as possible and take your next scheduled dose at your usual time the next day. **Do not take two doses on the same day to make up for a missed dose.**

Possible side effects from using CAMZYOS:

These are not all the possible side effects you may have when taking CAMZYOS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with CAMZYOS may include:

- dizziness
- headache
- fainting
- fatigue
- cough
- nausea
- shortness of breath
- irregular or rapid heartbeat
- rash

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Heart Failure (a condition where the heart cannot pump blood with enough force): shortness of breath, fatigue and weakness, swelling in ankles, legs and feet, chest pain, cough, fluid retention, rapid weight gain, lack of appetite, nausea, rapid or irregular heartbeat, reduced ability to exercise.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature (15°C to 30°C).
- Keep out of reach and sight of children.

If you want more information about CAMZYOS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://www.bms.com/ca/en>, or by calling 1-866-463-6267.

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