

**‘Patient leaflet in accordance with the Pharmacists’ Regulations (Preparations) - 1986**

**This medicine is dispensed with a doctor’s prescription only**

**CAMZYOS® 2.5 mg  
CAMZYOS® 5 mg  
CAMZYOS® 10 mg  
CAMZYOS® 15 mg  
Capsules**

Active ingredient and quantity:

CAMZYOS 2.5 mg: each capsule contains 2.5 mg of mavacamten

CAMZYOS 5 mg: each capsule contains 5 mg of mavacamten

CAMZYOS 10 mg: each capsule contains 10 mg of mavacamten

CAMZYOS 15 mg: each capsule contains 15 mg of mavacamten

Inactive ingredients and allergens - see section ‘Important information about some of this medicine’s ingredients’, and section 6 ‘Additional information’.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

In addition to the leaflet, CAMZYOS also has a patient guide and patient card. The guide and card contain important safety information that you need to know and that you should follow before starting and during treatment with CAMZYOS. Carefully read the patient guide and card and also the patient leaflet before using this medicine. Keep the guide and the card in case you need to read them again.

**The most important information you should know about CAMZYOS**

**CAMZYOS may cause serious side effects, including:**

- **Heart failure**, a condition where the heart muscle cannot contract with enough force. Heart failure is a serious condition that can lead to death. You must have echocardiograms before taking your first dose and during your treatment with CAMZYOS to help your doctor understand how your heart is responding to CAMZYOS. People who develop a serious infection or irregular heartbeat have a greater risk of heart failure during treatment with CAMZYOS.  
Tell your doctor or get medical help right away if you develop new or worsening:
  - shortness of breath
  - chest pain
  - fatigue
  - swelling in your legs
  - a racing sensation in your heart (palpitations)
  - rapid weight gain
- **The risk of heart failure is also increased when CAMZYOS is taken with certain other medicines.** Tell your doctor about the medicines you take, both prescription and nonprescription medicines, before and during treatment with CAMZYOS. See ‘Interactions with other medicines’ in **section 2** and **section 4** for information about side effects.

**1. What is this medicine intended for?**

CAMZYOS is indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) with mild to significant symptoms during daily activity, to improve symptoms and functional capacity.

**Therapeutic group:** Medicines to treat the heart.

**What is obstructive hypertrophic cardiomyopathy (oHCM)**

Hypertrophic cardiomyopathy is a condition where the walls of the left heart chamber contract harder and become thicker than normal. As the walls thicken, they can block the flow of blood out of the heart and can also make the heart more stiff.

This obstruction makes it more difficult for blood to flow into and out of the heart and be pumped to the body with each heartbeat.

The symptoms of oHCM include: chest pain and shortness of breath (especially with physical exercise); tiredness, heart rhythm disorders, dizziness, feeling that you are about to faint, fainting and edema (swelling) of the ankles, feet, legs, abdomen and/or veins in the neck.

**How the medicine works**

CAMZYOS acts to reduce excess contraction of the heart muscle and the obstruction of blood flow to the body. As a result, CAMZYOS may improve your symptoms and your ability to be active.

**2. Before using this medicine**

**Do not use this medicine if:**

- You are sensitive (allergic) to mavacamten or to any of the other ingredients in this medicine (as listed in section 6).
- You are taking certain medicines that may increase or decrease the levels of the active ingredient (mavacamten) of the medicine in your blood when taken together with CAMZYOS. Ask your doctor if the medicines you are taking prevent you from taking CAMZYOS. See ‘Interactions with other medicines’.

**Special warnings about using this medicine**

**Before treatment with CAMZYOS, tell your doctor if:**

- you are pregnant or planning to become pregnant. See ‘Pregnancy and breastfeeding’ section.
- you are a breastfeeding woman or plan to breastfeed. See ‘Pregnancy and breastfeeding’ section.
- you take any other medicines, including nonprescription medicines (such as omeprazole or esomeprazole) and/or other medicines for treatment of obstructive hypertrophic cardiomyopathy (HCM), vitamins or herbal supplements. See ‘Interactions with other medicines’ section.
- you develop an infection.

**Children and adolescents**

This medicine is not intended for children and adolescents under the age of 18. There is no information on safety and efficacy of CAMZYOS in children.

**Tests and follow-up**

Your doctor will assess your heart function using an echocardiogram (an ultrasound of the heart) before administration of the first dose and

regularly during treatment with CAMZYOS. It is very important to have these periodic echocardiograms, because your doctor needs to check the effect of CAMZYOS on your heart. Your dose may change during treatment to improve your response to CAMZYOS or to reduce side effects.

**Interactions with other medicines**

• **Taking CAMZYOS with certain medicines may cause heart failure. Do not stop taking or change the dose of a medicine and do not start taking a new medicine without consulting your doctor.**

• **If you are taking, have recently taken or might take other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.**

Particularly if you are taking:

- cimetidine, omeprazole, esomeprazole, pantoprazole (medicines to reduce the level of acid in your stomach).
- clarithromycin and erythromycin (certain antibiotics for bacterial infections).
- itraconazole, fluconazole, ketoconazole, posaconazole and voriconazole (certain medicines for fungal infections).
- fluoxetine, fluvoxamine, citalopram (certain medicines used to treat depression).
- ritonavir, cobicistat, efavirenz (certain medicines for treatment of HIV infections).
- rifampicin (a medicine for bacterial infections like tuberculosis).
- apalutamide, enzalutamide, mitotane, ceritinib, idelalisib, ribociclib, tucatinib (medicines used to treat certain types of cancer).
- carbamazepine, phenytoin, phenobarbital and primidone (certain medicines for treatment of seizures or epilepsy).
- St. John’s wort (a herbal medicine for treatment of depression).
- verapamil and diltiazem (certain beta blockers or calcium channel blockers that affect your heart).
- disopyramide, ranolazine (certain medicines that help your heart be more resistant to abnormal electrical activity such as sodium channel blockers).
- ticlopidine (a medicine to prevent stroke and heart attack).
- letermovir (a medicine for treatment of CMV infections).
- norethindrone (a medicine to treat various menstrual problems).
- ethinyl estradiol and progestin (certain contraceptives that contain these active ingredients).
- prednisone (a steroid).
- midazolam (a medicine used for sedation).
- repaglinide, tolbutamide (certain medicines used to treat diabetes).

**Using this medicine and food**

Taking CAMZYOS with grapefruit juice may affect the levels of the medicine in your blood and increase the risk of heart failure. CAMZYOS may be taken with or without food.

**Pregnancy and breastfeeding**

**Pregnancy**

If you are pregnant or plan to become pregnant, consult your doctor before starting treatment with CAMZYOS. CAMZYOS may harm your unborn baby. Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with CAMZYOS.

**If you are a woman and able to become pregnant:**

- Your doctor will do a pregnancy test before you start treatment with CAMZYOS.
- You should use effective birth control during treatment with CAMZYOS and for 4 months after your last dose of CAMZYOS.
- CAMZYOS may reduce how well hormonal birth control works. Talk to your doctor about the use of effective forms of birth control during treatment with CAMZYOS.

**Breastfeeding**

It is not known if CAMZYOS passes into breast milk. If you are breastfeeding or plan to breastfeed, talk to your doctor about the best way to feed your baby during treatment with CAMZYOS.

**Driving and using machines**

CAMZYOS may have a small effect on your ability to drive and use machines. If you feel dizzy, do not drive a vehicle, use tools or machines.

**Important information about some of this medicine’s ingredients**

This medicine contains less than 1 mmol sodium (23 mg) per dose and is considered ‘sodium-free’.

**3. How to use this medicine?**

Start of treatment and course of treatment with CAMZYOS will be performed under the supervision of a cardiologist.

Always use this medicine according to your doctor’s instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Do not change your dose without consulting your doctor first.

Your doctor may change your dose, temporarily or permanently stop your treatment with CAMZYOS if you have certain side effects or if you are taking certain medicines.

**Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:**

- The recommended starting dose is 5 mg once daily without regard to food.
- Your doctor will assess your heart function using echocardiograms before your first dose and during treatment with CAMZYOS to understand how your heart is responding to treatment. Your dosage may change during treatment. Possible dosages: 2.5 mg, 5 mg, 10 mg or 15 mg once daily.
- The maximum dosage is 15 mg once daily.

**Do not exceed the recommended dose.**

**Method of administration**

Take CAMZYOS once daily. CAMZYOS may be taken with or without food.

The capsule should be swallowed whole. Do not break, open or chew the capsule, because there is no information about using the capsule this way.

**If you have accidentally taken a higher dose** or if a child has accidentally swallowed some medicine, talk to a doctor immediately or go to a hospital immediately. Take the medicine package and this leaflet with you.

**If you forget to take a dose of the medicine**

If you miss a dose of CAMZYOS, take it as soon as possible on the same day and take your next dose at your regularly scheduled time the next day. Do not take 2 doses on the same day to make up for a missed dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

**4. Side effects**

As with any medicine, using CAMZYOS may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

**Serious side effects**

• **Heart failure. See section ‘The most important information you should know about CAMZYOS’**

**Tell your doctor or get medical help right away** if you develop new or worsening:

- shortness of breath
- chest pain
- fatigue
- swelling in your legs
- a racing sensation in your heart (palpitations)
- rapid weight gain

These may be signs that your heart cannot contract with enough force, a condition that can be life-threatening and lead to heart failure.

**Other side effects include:**

**Very common side effects, effects that appear in more than 1 in 10 users:**

- dizziness

**Common side effects, effects that appear in 1-10 in 100 users:**

- fainting

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the ‘Reporting Side Effects of Drug Treatment’ link on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the blister and carton. The expiry date refers to the last day of that month.

**Storage conditions:**

- Store below 30°C.

**6. Additional information**

- In addition to the active ingredient, this medicine also contains:

Capsule content:

mannitol, croscarmellose sodium, silica colloidal hydrated, hypromellose, magnesium stearate.

Capsule shell:

CAMZYOS 2.5 mg capsules:

gelatin, titanium dioxide, black iron oxide, red iron oxide.

CAMZYOS 5 mg capsules:

gelatin, titanium dioxide, yellow iron oxide.

CAMZYOS 10 mg capsules:

gelatin, titanium dioxide, red iron oxide.

CAMZYOS 15 mg capsules:

gelatin, titanium dioxide, black iron oxide.

Printing ink:

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

**What the medicine looks like and contents of the pack**

CAMZYOS 2.5 mg: Gelatin capsules with a light purple opaque cap imprinted in black with “2.5 mg” and a white opaque body imprinted with “Mava” in black.

CAMZYOS 5 mg: Gelatin capsules with a yellow opaque cap imprinted in black with “5 mg” and a white opaque body imprinted with “Mava” in black.

CAMZYOS 10 mg: Gelatin capsules with a pink opaque cap imprinted in black with “10 mg” and a white opaque body imprinted with “Mava” in black.

CAMZYOS 15 mg: Gelatin capsules with a grey opaque cap imprinted in black with “15 mg” and a white opaque body imprinted with “Mava” in black.

CAMZYOS is provided as capsules packaged in a tray (blister) in the following pack sizes:

A pack containing 14 capsules.

A pack containing 28 capsules.

Not all pack sizes may be marketed.

**Registration holder’s name and address**

Bristol-Myers Squibb (Israel) Ltd.,

18 Aharon Bart St., PO Box 3361,

Kiryat Arye,

Petach Tikva 4951448

**Manufacturer’s name and address**

Bristol-Myers Squibb Company

Route 206 & Province Line Road, Princeton, New Jersey 08543, USA

Registration number of the medicine in the Ministry of Health’s National Drug Registry:

CAMZYOS 2.5 mg: 174-18-37419-99

CAMZYOS 5 mg: 174-19-37420-99

CAMZYOS 10 mg: 174-20-37421-99

CAMZYOS 15 mg: 174-21-37422-99

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