

Package leaflet: Information for the patient

CAMZYOS 2.5 mg hard capsules

CAMZYOS 5 mg hard capsules

CAMZYOS 10 mg hard capsules

CAMZYOS 15 mg hard capsules

mavacamten

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Your doctor will give you a Patient Card and Patient Guide. Read it carefully and follow the instructions on it.
- Always show the Patient Card to the doctor, pharmacist or nurse when you see them or if you go to hospital.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What CAMZYOS is and what it is used for
2. What you need to know before you take CAMZYOS
3. How to take CAMZYOS
4. Possible side effects
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1. What CAMZYOS is and what it is used for

What CAMZYOS is

CAMZYOS contains the active substance mavacamten. Mavacamten is a reversible cardiac myosin inhibitor, meaning that it changes the action of the muscle protein myosin in heart muscle cells.

What CAMZYOS is used for

CAMZYOS is used to treat adults with a type of heart disease called obstructive hypertrophic cardiomyopathy (oHCM).

About obstructive hypertrophic cardiomyopathy

Hypertrophic cardiomyopathy (HCM) is a condition where the walls of the left heart chamber (ventricle) contract harder and become thicker than normal. As the walls thicken they can block (obstruct) the flow of blood out of the heart and can also make the heart 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, a condition known as obstructive hypertrophic cardiomyopathy (oHCM). Symptoms of oHCM are: chest pain and shortness of breath (especially with physical exercise); tiredness, abnormal heart rhythms, dizziness, feeling that you are about to faint, fainting (syncope) and swelling of the ankles, feet, legs, abdomen and/or veins in the neck.

How CAMZYOS works

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

2. What you need to know before you take CAMZYOS

Do not take CAMZYOS if:

- you are allergic to mavacamten or any of the other ingredients of this medicine (listed in section 6).
- you are pregnant or a woman of childbearing potential not using effective contraception.
- if you are taking medicines which may increase the level of CAMZYOS in your blood such as:
 - oral medicines to treat fungal infections such as itraconazole, ketoconazole, posaconazole, voriconazole,
 - certain medicines to treat bacterial infections such as the antibiotics clarithromycin,
 - certain medicines to treat HIV infection such as cobicistat, ritonavir,
 - certain medicines to treat cancer such as ceritinib, idelalisib, tucatinib.

Ask your doctor if the medicine you are taking prevents you from taking mavacamten. See section “Other medicines and CAMZYOS”

Warnings and precautions

Routine tests

Your doctor will assess how well your heart is working (your heart function) using an echocardiogram (an ultrasound test that takes images of your heart) before your first dose and regularly during treatment with CAMZYOS. It is very important to keep these echocardiogram appointments, because your doctor needs to check the effect of CAMZYOS on your heart. Your treatment dose may need to be adjusted to improve your response or to reduce side effects.

If you are a woman who could become pregnant your doctor may perform a pregnancy test before starting treatment with CAMZYOS.

Your doctor may do a test to check how this medicine is broken down (metabolised) in your body as this may be used to guide your CAMZYOS treatment (see section 3).

Tell your doctor or pharmacist straight away:

- **if you get any of these symptoms during your treatment with CAMZYOS:**
 - new or worsening shortness of breath,
 - chest pain,
 - tiredness,
 - palpitations (a forceful heartbeat that may be rapid or irregular), or
 - leg swelling.These could be signs and symptoms of systolic dysfunction, a condition where the heart cannot pump with enough force, which can be life-threatening and lead to heart failure.
- **if you develop** a serious infection or irregular heart beat (arrhythmia) as this could increase your risk of developing heart failure.

Your doctor may need to do additional tests of your heart function, interrupt the treatment or change your dose, depending on how you feel.

Women of childbearing potential

If used during pregnancy, CAMZYOS can harm the unborn baby. Before you start treatment with CAMZYOS your doctor will explain the risk to you and ask you to do a pregnancy test in order to ensure that you are not pregnant. Your doctor will give you a card which explains why you should not become pregnant while taking CAMZYOS. It also explains what you should do to avoid becoming pregnant while you are taking CAMZYOS. You must use effective contraception during treatment and for 6 months after stopping treatment (see section “Pregnancy and breast-feeding”).

If you do become pregnant while taking CAMZYOS, tell your doctor straight away. Your doctor will stop treatment (see “If you stop taking CAMZYOS” in section 3).

Children and adolescents

Do not give this medicine to children (aged below 18 years) because the effectiveness and safety of CAMZYOS have not been studied in children and adolescents.

Other medicines and CAMZYOS

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some other medicines can affect the way CAMZYOS works.

Some medicines can increase the amount of CAMZYOS in your body and make it more likely for you to get side effects that may be severe. Other medicines can reduce the amount of CAMZYOS in your body and may reduce its beneficial effects.

In particular, before taking CAMZYOS tell your doctor or pharmacist if you are taking, have recently taken, or have changed the dose of any of the following medicines:

- some medicines used to reduce the amount of acid your stomach produces (cimetidine, omeprazole, esomeprazole, pantoprazole)
- antibiotics for bacterial infections (such as clarithromycin, erythromycin)
- medicines used to treat fungal infections (such as itraconazole, fluconazole, ketoconazole, posaconazole and voriconazole)
- medicines used to treat depression (such as fluoxetine, fluvoxamine, citalopram)
- medicines for HIV infections (such as ritonavir, cobicistat, efavirenz)
- rifampicin (an antibiotic for bacterial infections like tuberculosis)
- apalutamide, enzalutamide, mitotane, ceritinib, idelalisib, ribociclib, tucatinib (medicines used to treat certain types of cancer)
- medicines for fits (seizures) or epilepsy (such as carbamazepine and phenytoin, phenobarbital, primidone)
- St. John's wort (a herbal medicine for depression)
- medicines that affect your heart (such as beta blockers and calcium channel blockers e.g. verapamil and diltiazem)
- medicines that make your heart more resistant to abnormal activity (such as sodium channel blockers e.g. disopyramide)
- ticlopidine (a medicine to prevent heart attack and stroke)
- letermovir (a medicine to treat cytomegalovirus infections)
- norethindrone (a medicine to treat various menstrual problems)
- prednisone (steroid).

If you take or have taken any of these medicines, or have changed the dose, your doctor needs to closely monitor you, may need to change your dose of CAMZYOS, or consider alternative treatments.

If you are not sure whether you are taking any of the medicines mentioned above, ask your doctor or pharmacist before taking CAMZYOS. Before stopping or changing the dose of a medicine or starting a new medicine, tell your doctor or pharmacist.

Do not take any of the above medicines occasionally or once in a while (not on a regular schedule) since that could change the amount of CAMZYOS in your body.

CAMZYOS with food and drink

You should use caution when drinking grapefruit juice while on treatment with CAMZYOS as it may change the amount of CAMZYOS in your body.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Do not take CAMZYOS during pregnancy, for 6 months before getting pregnant, or if you are a woman who could become pregnant and you are not using effective contraception. CAMZYOS may cause harm to your unborn baby. If you are a woman who could become pregnant, your doctor will inform you about this risk and will check if you are pregnant before starting treatment and regularly

during treatment. Your doctor will give you a card which explains why you should not become pregnant while taking CAMZYOS. If you become pregnant, think you may be pregnant or planning to become pregnant while taking CAMZYOS, tell your doctor right away.

Breast-feeding

It is not known if CAMZYOS passes through breastmilk. You must not breast-feed while taking CAMZYOS.

Driving and using machines

Mavacamten may have a small effect on your ability to drive and use machines. If you feel dizzy while taking this medicine, do not drive a vehicle, cycle or use any tools or machines.

CAMZYOS contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take CAMZYOS

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

How much to take

The recommended starting dose is 2.5 mg or 5 mg taken by mouth once daily. Your doctor may do a test to check how this medicine is broken down (metabolised) in your body. The result may guide your CAMZYOS treatment. If you have liver problems, your doctor may also prescribe a reduced starting dose.

Your doctor will monitor how well your heart is working while you are taking CAMZYOS using echocardiograms and may change your dose (increase, lower, or temporarily stop) based on the results.

Your doctor will tell you how much CAMZYOS to take.

Your doctor will prescribe you a single daily dose of either 2.5 mg, 5 mg, 10 mg or 15 mg. The maximum single dose is 15 mg once daily.

Always take CAMZYOS as prescribed by your doctor.

The first echocardiogram will be done before you start treatment, and then again during follow-up visits at week 4, 8 and 12 to assess your response to CAMZYOS. Routine echocardiograms will then be done every 12 weeks. If your doctor changes your dose of CAMZYOS at any point, an echocardiogram will be done 4 weeks afterwards to make sure you are receiving a beneficial dose.

Taking this medicine

- Swallow the capsule whole with a glass of water at about the same time each day.
- You can take the medicine with food or between meals.

If you take more CAMZYOS than you should

If you take more capsules than you should, contact your doctor or go to a hospital straight away if you have taken 3 to 5 times the recommended dose. If possible, take the medicine pack and this leaflet with you.

If you forget to take CAMZYOS

If you forget to take CAMZYOS at the usual time, take your dose as soon as you remember on the same day and take your next dose at the usual time the next day. Do not take a double dose to make up for a forgotten capsule.

If you stop taking CAMZYOS

Do not stop taking CAMZYOS unless your doctor tells you to. If you wish to stop taking CAMZYOS, notify your doctor to discuss the best way to do so.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with CAMZYOS:

- new or worsening shortness of breath, chest pain, tiredness, palpitations (a forceful heartbeat that may be rapid or irregular), or leg swelling. These could be signs and symptoms of systolic dysfunction (a condition where the heart cannot pump with enough force), which can lead to heart failure and be life-threatening. (*Common side effect*)

Very common (may affect more than 1 in 10 people)

- dizziness
- difficulty breathing

Common (may affect up to 1 in 10 people)

- fainting

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store CAMZYOS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CAMZYOS contains

- The active substance(s) is mavacamten. Each hard capsule contains either 2.5 mg, 5 mg, 10 mg or 15 mg of mavacamten.

- The other ingredients are:
 - capsule content: silica, colloidal hydrated, mannitol (E421), hypromellose (E464), croscarmellose sodium (E468, see section 2 “CAMZYOS contains sodium”), magnesium stearate
 - capsule shell:
 - CAMZYOS 2.5 mg hard capsules*
gelatin, titanium dioxide (E171), iron oxide black (E172), iron oxide red (E172)
 - CAMZYOS 5 mg hard capsules*
gelatin, titanium dioxide (E171), iron oxide yellow (E172)
 - CAMZYOS 10 mg hard capsules*
gelatin, titanium dioxide (E171), iron oxide red (E172)
 - CAMZYOS 15 mg hard capsules*
gelatin, titanium dioxide (E171), iron oxide black (E172)
 - printing ink: iron oxide black (E172), shellac (E904), propylene glycol (E1520), ammonia solution, concentrated (E527), potassium hydroxide (E525).

What CAMZYOS looks like and contents of the pack

- The CAMZYOS 2.5 mg, approximately 18.0 mm in length, hard capsules (capsules) have a light purple opaque cap and white opaque body imprinted in black ink with “2.5 mg” on the cap and “Mava” on the body.
- The CAMZYOS 5 mg, approximately 18.0 mm in length, hard capsules (capsules) have a yellow opaque cap and white opaque body imprinted in black ink with “5 mg” on the cap and “Mava” on the body.
- The CAMZYOS 10 mg, approximately 18.0 mm in length, hard capsules (capsules) have a pink opaque cap and white opaque body imprinted in black ink with “10 mg” on the cap and “Mava” on the body.
- The CAMZYOS 15 mg, approximately 18.0 mm in length, hard capsules (capsules) have a grey opaque cap and white opaque body imprinted in black ink with “15 mg” on the cap and “Mava” on the body.

The hard capsules are packaged in aluminium foil blisters containing 14 hard capsules.

Each pack contains either 14 or 28 hard capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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