

CAMZYOS®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Camzyos?

Camzyos contains the active ingredient mavacamten. Camzyos is used to treat adults with symptomatic obstructive hypertrophic cardiomyopathy. This is a type of heart disease with a thickened muscle in the heart which makes it harder for blood to leave the heart. For more information, see Section [1. Why am I using Camzyos?](#) in the full CMI.

2. What should I know before I use Camzyos?

Do not use if you have ever had an allergic reaction to Camzyos or any of the ingredients listed at the end of the CMI.

Some medicines should NOT be used with Camzyos.

The risk of heart failure is increased when Camzyos is taken with certain other medicines. Tell your doctor about the medicines you take, including prescription, non-prescription and herbal medicines, before and during treatment with Camzyos. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Camzyos?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines can increase the levels of Camzyos in your body and make it more likely for you to get new side effects that are possibly severe. Some medicines can decrease the levels of Camzyos in your body which can reduce its beneficial effects.

It is important to check the list of medicines in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Camzyos?

Your doctor will tell you how much Camzyos to take. Camzyos should be taken once a day, by mouth (orally), and it does not matter if you take it with or without food. More instructions can be found in Section [4. How do I use Camzyos?](#) in the full CMI.

5. What should I know while using Camzyos?

Things you should do

- Remind any doctor (including surgeon), dentist or pharmacist you visit that you are using Camzyos. If you undergo major heart surgery this could increase your risk of developing heart dysfunction.
- Tell your doctor straight away if you get any of these symptoms during treatment:
 - new or worsening shortness of breath, chest pain, fatigue, palpitations (a sensation or awareness of your heart beating), or leg

	<p>swelling. These could be signs and symptoms of heart dysfunction or heart failure (a condition where the heart cannot pump with enough force), which can be life-threatening.</p> <p>- if you develop a serious infection or arrhythmia (irregular heart beat) as this could increase your risk of developing heart dysfunction.</p>
Things you should not do	<ul style="list-style-type: none">● Do not stop taking Camzyos unless your doctor tells you to. If you wish to stop taking Camzyos, notify your doctor and discuss the best way to discontinue.● Do not take Camzyos during pregnancy and for at least 4 months before getting pregnant. Camzyos may cause harm to your unborn baby.● Do not stop or change the dose of a medicine or start a new medicine

	<p>without telling your doctor.</p> <ul style="list-style-type: none"> • Do not drink grapefruit juice while on treatment with Camzyos
Driving or using machines	<ul style="list-style-type: none"> • If you feel dizzy while taking this medicine, do not drive a vehicle, cycle or use any tools or machines.

For more information, see Section [5. What should I know while using Camzyos?](#) in the full CMI.

6. Are there any side effects?

Camzyos can cause serious side effects, including: Heart failure with reduced ejection fraction. The most common side effect of Camzyos in clinical trials was dizziness. You may need medical attention if you get some of the side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: Before you take Camzyos, your doctor and pharmacist will make sure you understand how to take Camzyos safely, which will include returning for echocardiograms when advised by your doctor. Taking Camzyos with certain medicines or grapefruit juice may cause heart failure. Do not stop or change the dose of a medicine or start a new medicine without telling your doctor. Some medicines should not be used with Camzyos .

Camzyos[®] (kam zye' ose)

Active ingredient(s): *Mavacamten*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Camzyos. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Camzyos.**

Where to find information in this leaflet:

- [1. Why am I using Camzyos?](#)
- [2. What should I know before I use Camzyos?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Camzyos?](#)
- [5. What should I know while using Camzyos?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Camzyos?

Camzyos contains the active ingredient mavacamten.

Camzyos is used to treat adults with symptomatic obstructive hypertrophic cardiomyopathy (obstructive HCM).

Hypertrophic cardiomyopathy (HCM) is a condition where the walls of the heart chamber (left ventricle) contract harder and become thicker than normal. This can be caused by abnormal genes in the heart muscle or it may be due to unknown causes. As the walls thicken they can reduce (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 get pumped to the body with each heartbeat. When this happens, the disease is called obstructive hypertrophic cardiomyopathy (obstructive HCM). Symptoms of obstructive HCM are: chest pain and shortness of breath (especially with physical exercise); fatigue, abnormal heart rhythms, dizziness, feeling that you are about to faint, fainting (syncope) and

swelling in the ankle, feet, legs, abdomen and veins in the neck.

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

2. What should I know before I use Camzyos?

Warnings

Do not use Camzyos if:

- you are allergic to mavacamten, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Do not take Camzyos with the following medicines:

- fluconazole, voriconazole, ketoconazole, posaconazole, isavuconazole, itraconazole (medicines used to treat fungal infections)
- fluoxetine, fluvoxamine (medicines used to treat depression)
- clarithromycin, rifampicin (medicines used to treat bacterial infections)
- phenytoin, carbamazepine (medicines used to treat seizures or epilepsy)

- ritonavir, cobicistat, efavirenz (anti-viral medicines for hepatitis C or HIV)
- apalutamide, dabrafenib, enzalutamide, lorlatinib (medicines used to treat types of cancer)
- St. John's Wort (a herbal medicine for depression)

Check with your doctor if you have any other medical conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Pregnancy

Do not take Camzyos during pregnancy and for at least 4 months before getting pregnant. 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.

Contraception

You must use effective contraception during treatment with Camzyos and for at least 4 months after you stop treatment. Talk to your doctor about contraception methods that may be right for you while you are taking this medicine. Your doctor will check if you are pregnant before treatment, and may consider it throughout treatment with Camzyos.

If you do become pregnant while taking Camzyos, tell your doctor straight away.

Breast-feeding

It is not known if Camzyos passes through breastmilk. Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including prescription, non-prescription or herbal medicines.

This is because some other 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 new side effects that are possibly severe. Some medicines reduce the levels of Camzyos in your body and may reduce its beneficial effects.

In particular, do not take with the following medicines with Camzyos:

- fluconazole, voriconazole, ketoconazole, posaconazole, isavuconazole, itraconazole (medicines used to treat fungal infections)
- fluoxetine, fluvoxamine (medicines used to treat depression)
- clarithromycin, rifampicin (medicines used to treat bacterial infections)

- phenytoin, carbamazepine (medicines used to treat seizures or epilepsy)
- ritonavir, cobicistat, efavirenz (anti-viral medicines for hepatitis C or HIV)
- apalutamide, dabrafenib, enzalutamide, lorlatinib (medicines used to treat types of cancer)
- St. John's Wort (a herbal medicine for depression)

Tell your doctor or pharmacist if you are taking or have recently taken or changed the dose of any of the following medicines:

- medicines used to reduce the amount of acid in your stomach (e.g., omeprazole and esomeprazole)
- medicines used to treat bacterial infections (e.g., erythromycin)
- medicines used to treat types of cancer (e.g., crizotinib, vemurafenib)
- medicines that affect your heart (such as beta blockers and calcium channel blockers e.g. verapamil and diltiazem)
- medicines to treat nausea and vomiting from chemotherapy (e.g., aprepitant)
- immunosuppressants such as a medicine called cyclosporine
- medicines that improve wakefulness (e.g., armodafinil, modafinil)
- medicines that make your heart more resistant to abnormal activity (such as sodium channel blockers e.g. disopyramide)

Tell your doctor if you are using goldenseal (a herbal medicine) as it may affect the level of Camzyos in your body.

Your doctor needs to closely monitor you, and may need to change your dose of Camzyos, or consider alternative treatments if you are taking any of these medicines, or have changed the dose.

If you are not sure whether you are taking any of the medicines mentioned above, ask your doctor or pharmacist.

Before stopping or changing the dose of a medicine or starting a new medicine, tell your doctor or pharmacist.

4. How do I use Camzyos?

How much to take / use

The recommended starting dose is 5 mg taken by mouth once daily.

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 may change your dose, temporarily stop, or permanently stop your treatment with Camzyos if you have certain side effects.

Your doctor will tell you how much Camzyos to take.

The first echocardiogram will be done 4 weeks after the start of treatment, follow-up visits at week 8 and 12 will assess your response to Camzyos using echocardiograms. Routine echocardiograms will 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.

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.

Taking this medicine

- Swallow the capsule whole with a glass of water at about the same time each day.
- Do not chew, dissolve or open the capsules.
- You can take the medicine with food or between meals.

If you forget to use Camzyos

Camzyos should be used regularly at the same time each day. If you miss your dose 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 the dose you missed.

If you use too much Camzyos

If you think that you have used too much Camzyos, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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 and discuss the best way to discontinue. Camzyos may remain in the body for at least 4 months after you stop treatment. You may experience side effects from the drug after you stop treatment.

5. What should I know while using Camzyos?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.

- Tell any other doctors (including surgeons), dentists and pharmacists who are treating you that you are being treated with Camzyos. If you undergo major heart surgery this could increase your risk of developing heart dysfunction. Tell your doctor immediately if you become pregnant or plan to become pregnant while being treated with Camzyos.
- Use an effective method of contraception during treatment and for 4 months after stopping treatment.

Things you should not do

- Do not stop using this medicine unless your doctor tells you to.
- Do not stop or change the dose of a medicine or start a new medicine without telling your doctor.
- Do not drink grapefruit juice while on treatment with Camzyos as it may cause heart failure

Routine Tests

Your heart will be assessed by an echocardiogram (a type of test that takes images of your heart to see how well it is working) before your first dose and regularly during treatment with Camzyos. This is because your doctor needs to check how well your heart is working. It is very important to keep echocardiogram appointments to monitor the effect of Camzyos on your heart. Your treatment dose may need to be adjusted to achieve maximum benefit, whilst minimising side effects.

Call your doctor straight away:

- **if you get any of these symptoms during your treatment with Camzyos:** new or worsening

shortness of breath, chest pain, fatigue, palpitations (a sensation or awareness of your heart beating), or leg swelling. These could be signs and symptoms of heart dysfunction or heart failure, a condition where the heart cannot pump with enough force, which can be life-threatening.

- **if you develop** a serious infection or arrhythmia (irregular heart beat) as this could increase your risk of developing heart dysfunction.

Your doctor may need to additionally assess your heart function, interrupt the treatment or change your dose depending on how you feel.

Remind any doctor (including surgeon), dentist or pharmacist you visit that you are using Camzyos.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Camzyos affects you.

Camzyos may cause dizziness in some people. If you feel dizzy while taking this medicine, do not drive a vehicle, cycle or use any tools or machines.

Looking after your medicine

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. It is recommended to store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• new or worsening shortness of breath, chest pain, fatigue, palpitations (a sensation or awareness of your heart beating), or leg	Tell your doctor, pharmacist immediately if you get any of these symptoms during treatment with Camzyos.

Serious side effects	What to do
swelling. These could be signs and symptoms of heart dysfunction or heart failure, which can be life-threatening.	

Other side effects

Very Common side effects	What to do
<ul style="list-style-type: none"> • Dizziness 	Speak to your doctor if you have any of these side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Camzyos contains

Active ingredient (main ingredient)	Mavacamten
Other ingredients (inactive ingredients)	Capsule content: <ul style="list-style-type: none">• Silicon dioxide• Mannitol• Hypromellose• Croscarmellose Sodium• Magnesium Stearate Capsule shell: <ul style="list-style-type: none">• Gelatin• Titanium Dioxide• Black Iron Oxide• Red Iron Oxide• Yellow Iron Oxide

Do not take this medicine if you are allergic to any of these ingredients.

What Camzyos looks like

The Camzyos 2.5 mg, size 2 hard capsule has light purple opaque cap and white opaque body imprinted in black ink with "2.5 mg" on the cap and "Mava" on the body. (AUST R 386129)

The Camzyos 5 mg, size 2 hard capsule has yellow opaque cap and white opaque body imprinted in black ink with "5 mg" on the cap and "Mava" on the body. (AUST R 386128)

The Camzyos 10 mg, size 2 hard capsule has pink opaque cap and white opaque body imprinted in black ink with "10 mg" on the cap and "Mava" on the body. (AUST R 386127)

The Camzyos 15 mg, size 2 hard capsule has grey opaque cap and white opaque body imprinted in black ink with "15 mg" on the cap and "Mava" on the body. (AUST R 373115)

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

Each pack contains 28 hard capsules.

Who distributes Camzyos

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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