

INDICATION & SELECT IMPORTANT SAFETY **INFORMATION FOR CAMZYOS**

What is CAMZYOS?

CAMZYOS is a prescription medicine used to treat:

✓ adults with symptomatic obstructive hypertrophic cardiomyopathy (obstructive HCM). CAMZYOS may improve your symptoms and your ability to be active.

It is not known if CAMZYOS is safe and effective in children.

WARNING: RISK OF HEART FAILURE



CAMZYOS may cause serious side effects, including

Heart failure, a condition where the heart cannot pump with enough force, is a serious condition that can lead to death.

You must have echocardiograms before you take your first dose and during your treatment with CAMZYOS to help your healthcare provider understand how your heart is responding to CAMZYOS. Echocardiograms (echos) are imaging tests, a type of ultrasound study, which take pictures of your heart and show how well your heart is working.

People who develop a serious infection or an irregular heartbeat have a greater risk of heart failure during treatment with CAMZYOS.



Get medical help right away if you experience new or worsening symptoms, including:

- shortness of breath
- chest pain
- fatique
- racing heart (palpitations)
- leg swelling
- rapid weight gain

The risk of heart failure is also increased when CAMZYOS is taken with certain other medications. Tell your healthcare provider about the medicines you take, both prescribed and obtained over-the-counter, before and during treatment with CAMZYOS.

Because of the serious risk of heart failure. CAMZYOS is only available through a restricted program called the CAMZYOS Risk **Evaluation and Mitigation Strategy (REMS) Program.** This means:

- You and your healthcare provider must both be enrolled in the CAMZYOS REMS program in order to have it prescribed. Talk to your healthcare provider about how to enroll and for more information about the program.
- - Your healthcare provider and pharmacist will make sure you understand how to take CAMZYOS safely, which includes returning for echos when advised by your healthcare provider.
- You can get CAMZYOS only from a certified pharmacy that is part of the CAMZYOS REMS program. Talk to your healthcare provider about finding a certified pharmacy. You will not be able to get CAMZYOS from a local pharmacy.
 - If you have questions about the CAMZYOS REMS Program. ask your healthcare provider, visit www.CAMZYOSREMS.com or call 1-833-628-7367.

Please see Important Safety Information, including **Boxed WARNING**, on pages 7–9 and US Full Prescribing Information and Medication Guide for CAMZYOS® (mavacamten).

Questions about your symptoms

Please complete the questions below and use the symptom-tracking calendar on pages 4 and 5 to record your obstructive HCM symptoms over time. Then bring this to your next doctor appointment.

It's important to keep your doctor up to date on how you're feeling. The symptom tracker in this guide can help you record your symptoms over time so you can share them with your doctor.

While the symptoms listed below are common symptoms of symptomatic obstructive HCM, people with this condition may experience additional symptoms that are not represented here. Symptoms can be representative of many conditions. Only a healthcare provider can assess these symptoms.

1. How would you summarize your symptoms? Check all that apply. How long has this symptom been present? **Date of most** How often do you **Symptom** experience this symptom? recent occurrence Shortness of breath Tiredness Chest pain Rapid heartbeat Dizziness Fainting Include additional details about your symptoms and their impact here.

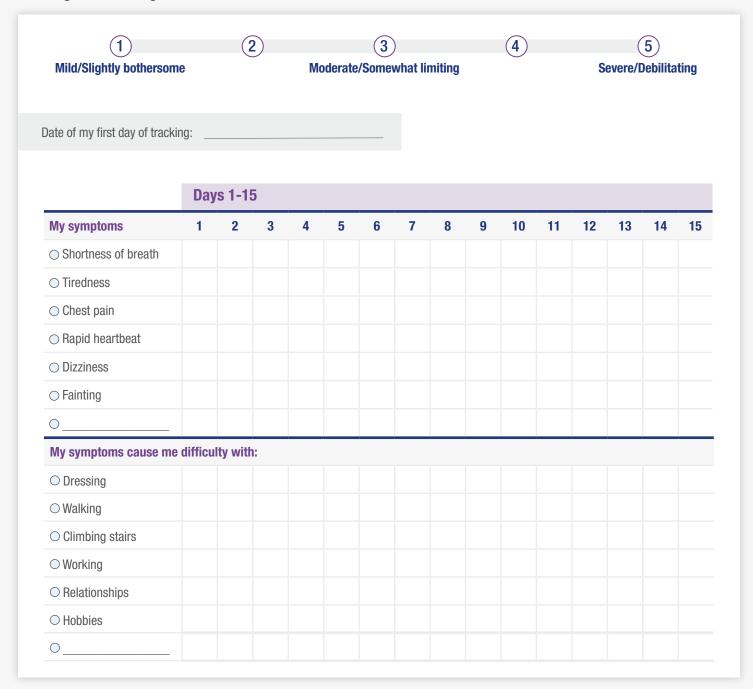
Full name: 2. Have the severity a	Today's o		changed rec	ently?
If so, how and wher	-		.	
3. How much of an im to participate in bot Circle a number belo	h daily tasks ar	nd leisure activiti	es?	-
1 Mild/Slightly bothersome	2 Mode	3 rate/Somewhat limiting	4	5 Severe/Debilitating
•		mpact of your sympton lost appropriate treatn		
nclude additional details abo	ut your symptoms ar	nd their impact here.		
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Your symptom-tracking calendar

In order to better understand how your symptoms are affecting your daily activities, you may find it helpful to track the frequency and severity of your symptoms over time. A daily symptom tracker has been provided below, but you can also track your symptoms using a notebook or the calendar on your phone.

Although the symptoms listed in this tracker are common symptoms of symptomatic obstructive HCM, people with this condition may experience additional symptoms that are not represented here. Symptoms can be representative of many conditions. Only a healthcare provider can assess these symptoms.

To use the tracker, write down each time you experience a symptom, and rate the severity/impact of each symptom from 1–5 according to the following scale:



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	Day	s 16-3	30												
My symptoms	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
○ Shortness of breath															
○ Tiredness															
Chest pain															
○ Rapid heartbeat															
○ Dizziness															
○ Fainting															
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My symptoms cause me	e difficul	lty with):												
○ Dressing															
○ Walking															
O Climbing stairs															
○ Working															
○ Relationships															
○ Hobbies															
O															

Questions about your symptoms (continued)

Include additional details about your symptoms and their impact here.	
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Important Facts About CAMZYOS®

This is a summary of important information that you need to know about CAMZYOS. Your healthcare provider can work with you to help answer any questions you may have about this medication. Keep this information in a safe place so you can refer to it before and during your treatment.

Look out for the following icons as you read:



Talk to your healthcare provider



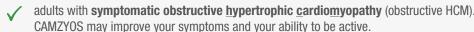
Call a healthcare provider



Helpful information to remember

What is CAMZYOS?

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- shortness of breath
- fatique

leg swelling

chest pain

- racing heart (palpitations)
- · rapid weight gain

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 Talk to your healthcare provider about finding a certified pharmacy. You will not be able to get CAMZYOS from a local pharmacy.
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Important Facts About CAMZYOS® (continued)

What should I discuss with my healthcare provider before starting CAMZYOS?



Talk to your healthcare provider about all of your medical conditions, including if:



You are pregnant or plan to become pregnant – CAMZYOS may harm your unborn baby



Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with CAMZYOS. You may also report your pregnancy by calling Bristol Myers Squibb at 1-800-721-5072 or by visiting www.bms.com.

If you are a female and able to become pregnant, your healthcare provider will do a pregnancy test before you start taking CAMZYOS. You should use an effective method of birth control (contraception) during treatment and for at least 4 months after your last dose of CAMZYOS.



CAMZYOS may reduce how well hormonal birth control works. Talk to your healthcare provider about the use of effective forms of birth control during treatment with CAMZYOS.



You are breastfeeding or plan to breastfeed

It is not known if CAMZYOS passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with CAMZYOS.

What medicines should I discuss with my healthcare provider?



Tell your healthcare provider about all of the medicines you take before and during treatment with CAMZYOS, including:



herbal supplements

Taking CAMZYOS with certain medicines or grapefruit juice may cause heart failure.



Especially tell your healthcare provider if you:

- take over-the-counter medicines, including medications like omeprazole (for example, Prilosec®), esomeprazole (for example, Nexium®), or cimetidine (for example, Tagamet®)
- take other medicines to treat your obstructive HCM disease
- develop an infection



Do not stop or change the dose of a medicine or start a new medicine without telling your healthcare provider.

What are the serious side effects of CAMZYOS?

A serious side effect is a side effect that can sometimes become life-threatening and can lead to death.



CAMZYOS may cause serious side effects, including heart failure (a condition where the heart cannot pump with enough force).



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- shortness of breath

leg swelling

- chest pain
- racing heart (palpitations)
- · rapid weight gain

What are the most common side effects?

The most common side effects of CAMZYOS include dizziness and fainting (syncope).



Tell your healthcare provider if you have any side effect that bothers you or that does not go away

These are not all of the possible side effects of CAMZYOS.



Talk to your healthcare provider for more information about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Bristol Myers Squibb at 1-800-721-5072.

How should I take CAMZYOS?



Before starting treatment with CAMZYOS, your healthcare provider will do an echocardiogram (echo) to assess your obstructive HCM. Your heart must be regularly monitored with echos while on treatment to help your healthcare provider understand how your heart is responding to CAMZYOS.



Talk to your healthcare provider for more information about echos and your echo schedule.



CAMZYOS comes in immediate release capsules, containing 2.5, 5, 10, or 15 mg of mavacamten. Each capsule is marked with the word MAVA and the number of milligrams (mg) it contains.

Inactive ingredients: croscarmellose sodium, hypromellose, magnesium stearate (non-bovine), mannitol, and silicon dioxide. Capsule: contains black iron oxide, gelatin, red iron oxide, titanium dioxide, and yellow iron oxide.

Take CAMZYOS exactly as your healthcare provider tells you.

- 1 time a day, by mouth
- X Do not break, open, bite, or chew the capsule
- Swallow the capsule whole
- X Do not change your dose of CAMZYOS without talking to your healthcare provider first



Talk to your healthcare provider about the right dose for you.

What if I miss a dose?

- Take it as soon as possible 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.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop your treatment with CAMZYOS if you have certain side effects.

What if I take too much CAMZYOS?



Call your healthcare provider or go to the nearest hospital emergency room right away.

How should I store CAMZYOS?

Store CAMZYOS capsules between 68°F-77°F (20°C-25°C). Keep CAMZYOS and all medicines out of the reach of children.





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