

**Doctor Discussion Guide:** Questions to help guide your discussion with your doctor

# CAMZYOS IS THE FIRST AND ONLY FDA-APPROVED TREATMENT OF ITS KIND\* FOR ADULTS WITH SYMPTOMATIC OBSTRUCTIVE HCM.

\*CAMZYOS is a cardiac myosin inhibitor.

# **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.

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 breathchest pain
- fatique
- leg swelling
- - racing heart (palpitations)
  - 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 additional Important Safety Information throughout, including Boxed WARNING, U.S. Full Prescribing Information, and Medication Guide for CAMZYOS.

# Questions to ask your doctor about your condition during your appointment

When you are having a conversation with your doctor, you can use this guide to help you:

Be prepared. There are questions in this guide that can help you prepare for your appointment. Having answers ready for these questions ahead of time may help you talk with your doctor about the impact of your condition and your treatment plan.

Become confident asking questions. Asking for clear answers from your doctor will help you work together to make informed decisions.

Take notes. You may want to take notes during your conversation so that you can refer to them later.

If you're newly diagnosed, you may want to ask your doctor about your symptomatic obstructive HCM diagnosis to better understand your condition and treatment options. Some questions are provided below to help you get the conversation started. Keep in mind that the questions provided are suggestions for topics you can discuss and are not meant as medical advice. Be sure to discuss any questions you have with your doctor.

| I. What is obstructive | HOW!!                 |                      |                         |  |
|------------------------|-----------------------|----------------------|-------------------------|--|
| 2. What may be causir  | ng my symptoms?       |                      |                         |  |
| 3. What may be the ca  | use of this condition | ?                    |                         |  |
| 1. What does this diag | nosis mean for me a   | nd my family?        |                         |  |
| 5. Is there another me | dical professional wh | no should be involve | d in my treatment plan? |  |

# **Preparing for your appointment**

You can fill out this section before you speak with your doctor to ensure you're ready to share important information about your history with symptomatic obstructive HCM and your current treatment plan.

If you're seeing a new doctor or specialist, be sure to answer questions 1 to 3 to help bring them up to date on what you're doing (or have done up until now) to help manage your condition. Also share any other relevant health history including medicines you are taking, pregnancy, or breastfeeding.

| 1. Do you currently manage your symptomatic obstructive HCM with medicine? (Please include prescription and over-the-counter medicines, including vitamins and herbal supplements.) If "Yes," please list:  | ○ Yes | ○ No |
|---|-------|------|
| 2. Do you take any medicines for other conditions?  (Please consider all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Include those you don't take every day—for example, acid reducers.)  If "Yes," please list: | ○ Yes | ○ No |
| 3. Have you had any procedures and/or surgeries for your obstructive HCM? (Examples may include alcohol septal ablation, myectomy, and ICD placement.) If "Yes," please list:   | ○ Yes | ○ No |
|   |       |      |

# **Preparing for your appointment (continued)**

Even if you're seeing the same doctor who diagnosed you, answering the following questions can help your doctor understand how you are feeling and what your treatment goals are.

| ii 100, doc tilo quodiono bolow  | to describe the impact of your symptoms.   |  |  |  |
|--|--|--|--|--|
| or have worsened duri  | structive HCM symptoms have a ng the past 2 months?  |  |  | periencing.                                  |
| <ul> <li>Shortness of breath</li> </ul>  | ○ Chest pain ○ Tiredn  | ess  | Other  |  |
| <ul> <li>Rapid heartbeat</li> </ul>  | O Dizziness O Faintin  | g  |  |  |
| may experience additional symptons only a healthcare provider can define the following   | e are common symptoms of symptomatic obst<br>toms that are not represented here. Symptoms<br>etermine whether these symptoms indicate of<br>aspects of your everyday life ha   | s can be repostructive HC  | resentative of many cond<br>CM or another condition.   | litions.                                     |
| may experience additional symptonic only a healthcare provider can do not be seen to be seen a seen and seen an | toms that are not represented here. Symptoms etermine whether these symptoms indicate of aspects of your everyday life ha  | s can be represented the can be represented to the can be can be represented to the can be represented to the can be repre | resentative of many cond<br>CM or another condition.   | symptoms                                     |
| may experience additional symptonic only a healthcare provider can describe the following during the past 2 week.  Check all that apply. This is a list  | toms that are not represented here. Symptoms etermine whether these symptoms indicate of aspects of your everyday life has?  | s can be represented by your content of the care of th | resentative of many cond<br>CM or another condition.   | symptoms<br>t include all                    |
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| may experience additional symptonly a healthcare provider can describe the following during the past 2 week.  Check all that apply. This is a list activities where you feel limited.  Dressing  Showering or bathing  Taking a short walk  Climbing a flight of stairs  | aspects of your everyday life has seed to common activities that may have been important or jogging (as if to catch a but of Doing yard work   | ave been  acted by you   | resentative of many condition.  Mor another condition.  Ilimited by your solution with the condition of the condition.  Hobbies or recreational visiting friends or family   | symptoms t include all activities            |
| may experience additional symptonly a healthcare provider can describe the following during the past 2 week.  Check all that apply. This is a list activities where you feel limited.  Dressing  Showering or bathing  Taking a short walk   | aspects of your everyday life has seen aspects of your everyday life has seen aspects of your everyday life has seen as a seen | ave been  acted by you   | resentative of many condition.  Mor another condition.  Ilimited by your solution with the solution of the sol | symptoms t include all activities ly ed ones |

# Questions to ask about CAMZYOS® during your appointment

**CAMZYOS** is a prescription medicine used to treat symptomatic obstructive hypertrophic cardiomyopathy, or HCM. CAMZYOS may improve your symptoms and your ability to be active.

If you're talking with a doctor about possible treatment options and want to learn more about CAMZYOS, here are some questions you may want to ask:

| 2. How does CAMZYOS work differently?                    |  |
|--|--|
| 3. What are the potential benefits and risks of CAMZYOS? |  |
| 4. How is CAMZYOS taken?                                 |  |

# **Important Facts about CAMZYOS**

## **How should I take CAMZYOS?**

Take CAMZYOS exactly as your healthcare provider tells you.

- √ 1 time a day, by mouth
- **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.

Please see additional Important Safety Information throughout, including **Boxed WARNING**, U.S. Full Prescribing Information, and Medication Guide for CAMZYOS.

# Questions to ask about CAMZYOS® during your appointment (continued)

| 5. What are the monitoring and safety requireme and Mitigation Strategy, or REMS, program?   | ents of the CAMZYOS Risk Evaluation                           |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
| 6. Where would I receive my echocardiograms, and how would we schedule them?   |   |  |  |  |  |  |  |
| 7. What are the side effects of CAMZYOS, and is there anything else, such as a Boxed WARNING, that I should know about?  |   |  |  |  |  |  |  |
| If you and your doctor are considering CAMZYOS, be surprescription medicines, and over-the-counter medicine. Your doctor is always the best source of information when the state of the sta | s, including vitamins and herbal supplements.                 |  |  |  |  |  |  |
| mportant next steps to know if your doctor prescribes CAMZYOS  |   |  |  |  |  |  |  |
| t's possible your doctor may prescribe CAMZYOS for your condition. The following checklist includes topics you may want to discuss with your doctor before starting on CAMZYOS:  |   |  |  |  |  |  |  |
| Enrolling in the CAMZYOS REMS program  | O Developing an infection                                     |  |  |  |  |  |  |
| <ul> <li>All the medicines you take, including prescription<br/>and over-the-counter medicines, vitamins, and herbal</li> </ul>  | How to get CAMZYOS from a specialty pharmacy                  |  |  |  |  |  |  |
| supplements (even if you don't take them every day)  | Scheduling and attending regular echocardiograms              |  |  |  |  |  |  |
| <ul> <li>Dietary restrictions to be aware of when taking CAMZYOS,<br/>such as avoiding grapefruit juice</li> </ul>   | <ul> <li>Ask about what resources may be available</li> </ul> |  |  |  |  |  |  |
| <ul> <li>Pregnancy or plans to become pregnant, breastfeeding,<br/>and effective forms of birth control during treatment</li> </ul>  |   |  |  |  |  |  |  |

# **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:



healthcare provider



Call a healthcare provider right away



**Helpful information** to remember

## 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.

# **WARNING: RISK OF HEART FAILURE**

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



**CAMZYOS** may cause serious side effects, including heart failure.

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 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

leg swelling

chest pain

- racing heart (palpitations)
- 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:

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- - 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.

# 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 <a href="https://www.bms.com">www.bms.com</a>.

If you are a female and are 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:

prescription medicinesvitamins

over-the-counter medicines

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).



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

- · 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.



#### What if I take too much CAMZYOS?

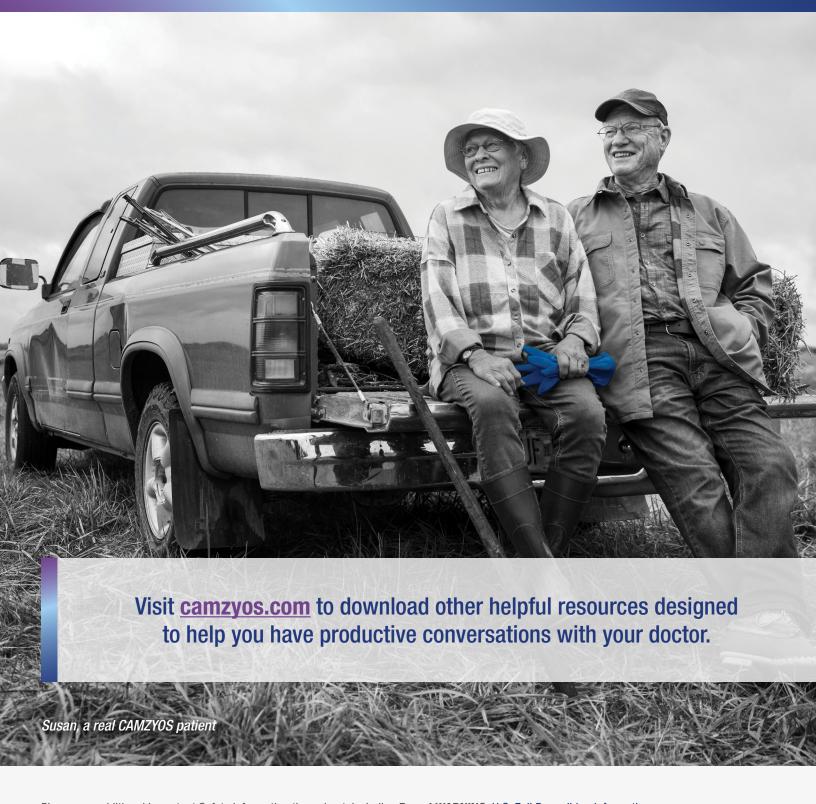


Call your healthcare provider or go to the nearest hospital emergency room right away

#### **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.





Please see additional Important Safety Information throughout, including **Boxed WARNING**, <u>U.S. Full Prescribing Information</u>, and **Medication Guide** for CAMZYOS.

