

**MEDICATION GUIDE**  
**CAMZYOS® (kam-zai-ōs)**  
**(mavacamten)**  
**capsules, for oral use**

**What is the most important information I should know about CAMZYOS?**

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

- **Heart failure**, a condition where the heart cannot pump with enough force. Heart failure 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. People who develop a serious infection or irregular heartbeat have a greater risk of heart failure during treatment with CAMZYOS.

Tell your healthcare provider 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 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.**
    - Your healthcare provider must be enrolled in the CAMZYOS REMS Program in order for you to be prescribed CAMZYOS.
    - Before you take CAMZYOS, you must enroll in the CAMZYOS REMS Program. Talk to your healthcare provider about how to enroll in the CAMZYOS REMS Program. You will be given information about the program when you enroll.
    - Before you take CAMZYOS, your healthcare provider and pharmacist will make sure you understand how to take CAMZYOS safely, which will include returning for echocardiograms when advised by your healthcare provider.  
CAMZYOS can only be dispensed by a certified pharmacy that participates in the CAMZYOS REMS Program. Your healthcare provider can give you information on how to find a certified pharmacy. You will not be able to get CAMZYOS at a local pharmacy.
    - If you have questions about the CAMZYOS REMS Program, ask your healthcare provider, go to [www.CAMZYOSREMS.com](http://www.CAMZYOSREMS.com), or call 1-833-628-7367.

See “**What are the possible side effects of CAMZYOS?**” for information about side effects.

**What is CAMZYOS?**

CAMZYOS is a prescription medicine used to treat adults with symptomatic obstructive hypertrophic cardiomyopathy (HCM). CAMZYOS may improve your symptoms and your ability to be active. It is not known if CAMZYOS is safe and effective in children.

**Before taking CAMZYOS, tell 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 may be pregnant during treatment with CAMZYOS. You may also report your pregnancy by calling Bristol-Myers Squibb at 1-800-721-5072 or [www.bms.com](http://www.bms.com).

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

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

**Before and during CAMZYOS treatment, tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. 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 healthcare provider.**

**Especially tell your healthcare provider if you:**

- Take over-the-counter medicines such as 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

**How should I take CAMZYOS?**

- Take CAMZYOS exactly as your healthcare provider tells you to take it.
- Do not change your dose of CAMZYOS without talking to your healthcare provider first.
- Take CAMZYOS 1 time a day.
- Swallow the capsule whole. Do not break, open, or chew the capsule.
- If you miss a dose of CAMZYOS, 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.
- If you take too much CAMZYOS, call your healthcare provider or go to the nearest hospital emergency room right away.

**What are the possible side effects of CAMZYOS?****CAMZYOS may cause serious side effects, including:**

- **Heart failure.** See “What is the most important information I should know about CAMZYOS?”

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

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

Call your doctor for medical advice 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 store CAMZYOS?**

Store CAMZYOS at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep CAMZYOS and all medicines out of the reach of children.**

**General information about the safe and effective use of CAMZYOS.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CAMZYOS for a condition for which it was not prescribed. Do not give CAMZYOS to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about CAMZYOS that is written for health professionals.

**What are the ingredients in CAMZYOS?**

**Active ingredient:** mavacamten

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

Marketed by:  
Bristol-Myers Squibb Company  
Princeton, NJ 08543 USA

CAMZYOS® is a trademark of MyoKardia, Inc., a Bristol Myers Squibb company.

For more information, go to [www.CAMZYOS.com](http://www.CAMZYOS.com) or call 1-800-721-5072.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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