

CAMZYOS® REMS Patient Brochure



CAMZYOS™
(mavacamten)_{2.5, 5, 10, 15mg}
capsules

What Is CAMZYOS® (mavacamten)?

CAMZYOS is a prescription medicine used to treat adult patients with symptomatic obstructive hypertrophic cardiomyopathy, a heart condition.

What Is the Most Serious Risk of Treatment With CAMZYOS?

In some patients, CAMZYOS can cause heart failure due to systolic dysfunction, when the heart is unable to pump enough blood to the body. Heart failure is a serious condition that can lead to death.

Tell your healthcare provider right away if you have new or worsening symptoms of heart failure while taking CAMZYOS. If you cannot reach your healthcare provider, seek urgent or emergency healthcare right away.

Symptoms of heart failure include:

- Shortness of breath
- Chest pain
- Fatigue
- A racing sensation in your heart (palpitations)
- Swelling in your legs
- Rapid weight gain

Drug Interactions

The risk of heart failure can increase for people who are taking certain medicines or supplements with CAMZYOS. These medicines can affect the amount of CAMZYOS in their blood. Your healthcare provider will discuss these interactions with CAMZYOS, including examples of which over-the-counter medicines and supplements to avoid.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements, even if you don't take them every day. Do not start taking a new medicine, stop existing medicines, or change the dose of any of your medicines without talking to your healthcare provider. CAMZYOS and other medicines may affect each other, causing side effects.

What Do I Need to Do to Take CAMZYOS?

Before Taking CAMZYOS

1. **Receive and review** this brochure with your healthcare provider and ask any questions you may have.
2. **Discuss** with your healthcare provider and understand the:
 - Risk of heart failure due to systolic dysfunction, when your heart is unable to pump enough blood to the body

- Symptoms of heart failure
- Need to report new or worsening symptoms of heart failure to your healthcare provider or to seek other medical attention
- Risks of CAMZYOS interacting with other medicines, including over-the-counter medicines and supplements
- Need to get regular echocardiograms

3. **Tell** your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.
 - Do not start taking a new medicine or change the dose of any of your medicines without talking to your healthcare provider
 - On the next page are **some examples** of medicines and supplements that can affect the amount of CAMZYOS in your blood and that should be avoided. These examples are a guide and not a complete list of all possible drugs that may fit this category
4. **Get** an echocardiogram to see if you are eligible for treatment with CAMZYOS.
5. **Complete** the **Patient Enrollment Form** with your healthcare provider.
6. **Notify** your healthcare provider if you delay taking your first dose of CAMZYOS more than 7 days after receiving your first prescription of CAMZYOS from the pharmacy.

While Taking CAMZYOS

7. **Get** regular echocardiograms as directed on the next page. Your healthcare provider will decide if your CAMZYOS dose needs to be changed. If you do not get these echocardiograms, you will not be able to continue to receive CAMZYOS.

Where Will I Get My CAMZYOS Medicine?

CAMZYOS is only dispensed by pharmacies that participate in the REMS. CAMZYOS is not available through local retail pharmacies.

The pharmacy will contact you to fill your prescription and ship it to your home.

Be sure to tell the pharmacist about any new medicine or changes in the dose of the medicines you are taking, including over-the-counter medicines and supplements.

Examples of Drug Interactions for CAMZYOS

Over-the-counter

Grapefruit juice	Nexium (esomeprazole)	Prilosec (omeprazole)	St. John's wort
Tagamet (cimetidine)			

Prescription

Biaxin (clarithromycin)	Intelence (etravirine)	Nydrazid (isoniazid)	Tagamet (cimetidine)
Cerebyx (fosphenytoin)	Luminal (phenobarbital)	Phenobarbital	Tegretol (carbamazepine)
Calan (verapamil)	Luvox (fluvoxamine)	Prilosec (omeprazole)	Ticlid (ticlopidine)
Cardizem (diltiazem)	Lysodren (mitotane)	Prozac (fluoxetine)	Tracleer (bosentan)
Cipro (ciprofloxacin)	Multaq (dronedarone)	Rifadin (rifampin)	Tybost (cobicistat)
Diflucan (fluconazole)	Mysoline (primidone)	Ritonavir-containing products (eg, Norvir, Paxlovid, Kaletra)	Vfend (voriconazole)
Dilantin (phenytoin)	Nafcillin	Serzone (nefazodone)	Viracept (nelfinavir)
Erleada (apalutamide)	Nexium (esomeprazole)	Sporanox (itraconazole)	Xtandi (enzalutamide)
Erythromycin	Nizoral (ketoconazole)	Sustiva (efavirenz)	Zydelig (idelalisib)
Felbatol (felbamate)	Noxafil (posaconazole)		

Echocardiogram Requirements for CAMZYOS



Before
treatment
starts



At 4 weeks
after treatment
is started



At 8 weeks
after treatment
is started



At 12 weeks
after treatment
is started



Every 3 to 6 months thereafter
(depending on
echocardiogram
results)

Echocardiograms may also be needed:

- 4 weeks and 12 weeks after a change in the dose of CAMZYOS
- After a break in treatment (as directed by your healthcare provider)
- 4 weeks and 12 weeks after starting certain medicines that are known to affect CAMZYOS

Your healthcare provider will let you know if these echocardiograms are required.

What Is the CAMZYOS REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are greater than the risks. FDA must approve these steps as part of the REMS.

CAMZYOS has a REMS because of the risk of heart failure due to systolic dysfunction.

Where Can I Get More Information on CAMZYOS?

You can find additional information at **CAMZYOSREMS.com** or call CAMZYOS REMS at 833-628-7367.



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