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

The Growing Body of Evidence for CAMZYOS®

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Program Information:

Date:
Tuesday, November 11, 2025

Meeting time (time zone):
6:00 PM - CST

Meeting ID:
251111-BMS-117777

Venue information:
Casa Mangiare
Glass Room
840 University Dr. E. , College Station, Texas 77840

RSVP Information:

Register for this program by visiting the following link or scanning the QR code:
https://myattendeeresource.com/BMS/251111-BMS-117777

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INDICATION

CAMZYOS® (mavacamten) is indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) Class II–III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF HEART FAILURE
CAMZYOS reduces left ventricular ejection fraction (LVEF) and can cause heart failure due to systolic dysfunction.

Echocardiogram assessments of LVEF are required prior to and during treatment with CAMZYOS. Initiation of CAMZYOS in patients with LVEF <55% is not recommended. Interrupt CAMZYOS if LVEF is <50% at any visit or if the patient experiences heart failure symptoms or worsening clinical status.

Concomitant use of CAMZYOS with certain cytochrome P450 inhibitors or discontinuation of certain cytochrome P450 inducers may increase the risk of heart failure due to systolic dysfunction; therefore, the use of CAMZYOS is contraindicated with the following:

- **Strong CYP2C19 inhibitors**
- **Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers**

Because of the risk of heart failure due to systolic dysfunction, CAMZYOS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the CAMZYOS REMS Program.

CONTRAINDICATIONS

CAMZYOS is contraindicated with concomitant use of:

- Strong CYP2C19 inhibitors
- Moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers

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Please see additional Important Safety Information, including **Boxed WARNING**, throughout and US Full Prescribing Information for CAMZYOS, or ask your sales representative.

IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS

Heart Failure

CAMZYOS reduces systolic contraction and can cause heart failure or significantly reduce ventricular function. Patients who experience a serious intercurrent illness (eg, serious infection) or arrhythmia (eg, atrial fibrillation or other uncontrolled tachyarrhythmia) are at greater risk of developing systolic dysfunction and heart failure.

Assess the patient's clinical status and LVEF prior to and regularly during treatment and adjust the CAMZYOS dose accordingly. New or worsening arrhythmia, dyspnea, chest pain, fatigue, palpitations, leg edema, or elevations in N-terminal pro-B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of heart failure and should also prompt an evaluation of cardiac function.

Asymptomatic LVEF reduction, intercurrent illnesses, and arrhythmias require additional dosing considerations.

Initiation of CAMZYOS in patients with LVEF <55% is not recommended. Avoid concomitant use of CAMZYOS in patients on disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker as these medications and combinations increase the risk of left ventricular systolic dysfunction and heart failure symptoms and clinical experience is limited.

CYP450 Drug Interactions Leading to Heart Failure or Loss of Effectiveness

CAMZYOS is primarily metabolized by CYP2C19 and CYP3A4 enzymes. Concomitant use of CAMZYOS and drugs that interact with these enzymes may lead to life-threatening drug interactions such as heart failure or loss of effectiveness.

Advise patients of the potential for drug interactions, including with over-the-counter medications (such as omeprazole, esomeprazole, or cimetidine). Advise patients to inform their healthcare provider of all concomitant products prior to and during CAMZYOS treatment.

CAMZYOS Risk Evaluation and Mitigation Strategy (REMS) Program

CAMZYOS is only available through a restricted program called the CAMZYOS REMS Program because of the risk of heart failure due to systolic dysfunction. Notable requirements of the CAMZYOS REMS Program include the following:

- Prescribers must be certified by enrolling in the REMS Program
- Patients must enroll in the REMS Program and comply with ongoing monitoring requirements
- Pharmacies must be certified by enrolling in the REMS Program and must only dispense to patients who are authorized to receive CAMZYOS
- Wholesalers and distributors must only distribute to certified pharmacies

Further information is available at www.CAMZYOSREMS.com or by telephone at 1-833-628-7367.

Embryo-Fetal Toxicity

CAMZYOS may cause fetal toxicity when administered to a pregnant female, based on animal studies. Confirm absence of pregnancy in females of reproductive potential prior to treatment and advise patients to use effective contraception during treatment with CAMZYOS and for 4 months after the last dose. Combined hormonal contraceptives (CHCs) containing a combination of ethinyl estradiol and norethindrone may be used with CAMZYOS. However, CAMZYOS may reduce the effectiveness of certain other CHCs. If these CHCs are used, advise patients to add nonhormonal contraception (such as condoms) during concomitant use and for 4 months after the last dose of CAMZYOS.

ADVERSE REACTIONS

In the EXPLORER-HCM trial, adverse reactions occurring in >5% of patients and more commonly in the CAMZYOS group than in the placebo group were dizziness (27% vs 18%) and syncope (6% vs 2%). There were no new adverse reactions identified in VALOR-HCM.

Effects on Systolic Function

In the EXPLORER-HCM trial, mean (SD) resting LVEF was 74% (6) at baseline in both treatment groups. Mean (SD) absolute change from baseline in LVEF was -4% (8) in the CAMZYOS group and 0% (7) in the placebo group over the 30-week treatment period. At Week 38, following an 8-week interruption of trial drug, mean LVEF was similar to baseline for both treatment groups. In the EXPLORER-HCM trial, 7 (6%) patients in the CAMZYOS group and 2 (2%) patients in the placebo group experienced reversible reductions in LVEF <50% (median 48%: range 35-49%) while on treatment. In all 7 patients treated with CAMZYOS, LVEF recovered following interruption of CAMZYOS.

DRUG INTERACTIONS

Potential for Other Drugs to Affect Plasma Concentrations of CAMZYOS

CAMZYOS is primarily metabolized by CYP2C19 and to a lesser extent by CYP3A4 and CYP2C9. Inducers and inhibitors of CYP2C19 and moderate to strong inhibitors or inducers of CYP3A4 may affect the exposures of CAMZYOS.

Impact of Other Drugs on CAMZYOS:

- Strong CYP2C19 Inhibitors: Concomitant use increases CAMZYOS exposure, which may increase the risk of heart failure due to systolic dysfunction. Concomitant use is contraindicated
- Moderate to Strong CYP2C19 Inducers or Moderate to Strong CYP3A4 Inducers: Concomitant use decreases CAMZYOS exposure, which may reduce CAMZYOS' efficacy. The risk of heart failure due to systolic dysfunction may increase with discontinuation of these inducers as the levels of induced enzyme normalizes. Concomitant use is contraindicated
- Weak CYP2C19 Inhibitors or Moderate CYP3A4 Inhibitors: Concomitant use with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor increases CAMZYOS exposure, which may increase the risk

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DRUG INTERACTIONS (cont'd)

of adverse drug reactions. Initiate CAMZYOS at the recommended starting dose of 5 mg orally once daily in patients who are on stable therapy with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Reduce dose of CAMZYOS by one level (ie, 15 to 10 mg, 10 to 5 mg, or 5 to 2.5 mg) in patients who are on CAMZYOS treatment and intend to initiate a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Schedule clinical and echocardiographic assessment 4 weeks after inhibitor initiation, and do not up-titrate CAMZYOS until 12 weeks after inhibitor initiation. Avoid initiation of concomitant weak CYP2C19 and moderate CYP3A4 inhibitors in patients who are on stable treatment with 2.5 mg of CAMZYOS because a lower dose is not available. For short-term use (eg, 1 week), interrupt CAMZYOS for the duration of treatment with a weak inhibitor of CYP2C19 or a moderate inhibitor of CYP3A4. CAMZYOS may be reinitiated at the previous dose immediately on discontinuation of concomitant therapy

- Moderate CYP2C19 Inhibitors or Strong CYP3A4 Inhibitors: Concomitant use with a moderate CYP2C19 inhibitor or strong CYP3A4 inhibitor increases CAMZYOS exposure, which may increase the risk of adverse drug reactions. Discontinuing use of a moderate CYP2C19 inhibitor or strong CYP3A4 inhibitor after long-term concomitant use may decrease CAMZYOS exposure, which may reduce CAMZYOS' efficacy. Initiate CAMZYOS at a starting dosage of 2.5 mg orally once daily in patients who are on a stable therapy with a moderate CYP2C19 inhibitor or a strong CYP3A4 inhibitor. Reduce dose of CAMZYOS by one level (ie, 15 to 10 mg, 10 to 5 mg, or 5 to 2.5 mg) in patients who are on CAMZYOS and intend to initiate a moderate CYP2C19 inhibitor or a strong CYP3A4 inhibitor. Avoid initiation of concomitant moderate CYP2C19 and strong CYP3A4 inhibitors in patients who are on a stable treatment with 2.5 mg of CAMZYOS because a lower dose is not available. An increase in dose of CAMZYOS may be needed if the moderate inhibitor of CYP2C19 or strong inhibitor of CYP3A4 is discontinued after long-term concomitant use. Monitor for new or worsening symptoms. For short-term use (ie, when CAMZYOS dose modification is not feasible), interrupt CAMZYOS for the duration of treatment with a weak inhibitor of CYP2C19 or a moderate inhibitor of CYP3A4. CAMZYOS may be reinitiated at the previous dose immediately on discontinuation of concomitant therapy

Potential for CAMZYOS to Affect Plasma Concentrations of Other Drugs

CAMZYOS is an inducer of CYP3A4, CYP2C9, and CYP2C19. Concomitant use with CYP3A4, CYP2C9, or CYP2C19 substrates may reduce plasma concentration of these drugs. Closely monitor when CAMZYOS is used with concomitant CYP3A4, CYP2C9, or CYP2C19 substrates unless otherwise recommended in the Prescribing Information.

Certain Combined Hormonal Contraceptives (CHCs): Progestin and ethinyl estradiol are CYP3A4 substrates. Concomitant use of CAMZYOS may decrease exposures of certain progestins, which may lead to contraceptive failure. CHCs containing a combination of ethinyl estradiol and norethindrone may be used with CAMZYOS, but if other CHCs are used, advise patients to add nonhormonal contraception (such as condoms) or use an alternative contraceptive method that is not affected by CYP450 enzyme induction (eg, intrauterine system) during concomitant use and for 4 months after the last dose of CAMZYOS.

Drugs That Reduce Cardiac Contractility

Expect additive negative inotropic effects of CAMZYOS and other drugs that reduce cardiac contractility. Avoid concomitant use of CAMZYOS in patients on disopyramide, ranolazine, verapamil with a beta blocker, or diltiazem with a beta blocker as these medications and combinations increase the risk of left ventricular systolic dysfunction and heart failure symptoms and clinical experience is limited.

If concomitant therapy with a negative inotrope is initiated, or if the dose of a negative inotrope is increased, monitor LVEF closely until stable doses and clinical response have been achieved.

SPECIFIC POPULATIONS

Pregnancy

CAMZYOS may cause fetal harm when administered to a pregnant female. Advise pregnant females about the potential risk to the fetus with maternal exposure to CAMZYOS during pregnancy. There is a pregnancy safety study for CAMZYOS. If CAMZYOS is administered during pregnancy, or if a patient becomes pregnant while receiving CAMZYOS or within 4 months after the last dose of CAMZYOS, healthcare providers should report CAMZYOS exposure by contacting Bristol Myers Squibb at 1-800-721-5072 or www.bms.com.

Lactation

The presence of CAMZYOS in human or animal milk, the drug's effects on the breastfed infant, or the effects on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CAMZYOS and any potential adverse effects on the breastfed child from CAMZYOS or from the underlying maternal condition.

Females and Males of Reproductive Potential

Confirm absence of pregnancy in females of reproductive potential prior to initiation of CAMZYOS. Advise females of reproductive potential to use effective contraception during treatment with CAMZYOS and for 4 months after the last dose. CHCs containing a combination of ethinyl estradiol and norethindrone may be used with CAMZYOS. However, CAMZYOS may reduce the effectiveness of certain other CHCs. If these CHCs are used, advise patients to add nonhormonal contraception (such as condoms) or use an alternative contraceptive method during concomitant use and for 4 months after the last dose of CAMZYOS.

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