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

CAMZYOS™ REMS
Program Overview

This overview describes the requirements of the CAMZYOS REMS and the responsibilities of healthcare providers, pharmacists, and patients.

What is the CAMZYOS REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a strategy to manage known or potential risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks.

Because of the serious risk of heart failure due to systolic dysfunction, CAMZYOS is available only through a restricted program called the CAMZYOS REMS.

CAMZYOS may increase the risk of heart failure due to systolic dysfunction; patients may experience heart failure at any time during treatment with CAMZYOS.

What are the requirements of the CAMZYOS REMS?

In order for patients to receive CAMZYOS, healthcare providers, pharmacies, and patients must comply with the requirements of the CAMZYOS REMS.

Phone: 833-628-7367
Fax: 833-299-9539
CAMZYOSREMS.com

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Healthcare Provider Requirements

Only healthcare providers certified in the CAMZYOS REMS are authorized to prescribe CAMZYOS.

Become Certified (One Time)

Before prescribing CAMZYOS:

1. Review the Prescribing Information
2. Review the following educational materials:
   - ***Program Overview*** (this document)
   - ***Education Program for Healthcare Providers and Pharmacies***
3. Successfully complete and submit the following to become certified:
   - ***Healthcare Provider Knowledge Assessment***
   - ***Healthcare Provider Enrollment Form***
4. Receive confirmation of CAMZYOS REMS certification

Enroll Patients

Before starting each patient on CAMZYOS:

1. Counsel the patient, using the ***Patient Brochure***, on the:
   - Risk of heart failure due to systolic dysfunction, including how to recognize and respond to the symptoms of heart failure due to systolic dysfunction
   - Risk of drug-drug interactions with CYP2C19 or CYP3A4 inhibitors and inducers and the need to inform healthcare providers of all the prescription and nonprescription medications they take
2. Provide the patient with the ***Patient Brochure***
3. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram
4. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions
5. Enroll the patient by completing the ***Patient Enrollment Form*** together with the patient and documenting and submitting the confirmation of the echocardiogram, screening for drug-drug interactions, and authorization for treatment to the REMS

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Healthcare Provider Requirements (continued)

At All Times for Each Patient

Once the patient is on CAMZYOS:

1. Counsel the patient on the risk of heart failure due to systolic dysfunction and drug-drug interactions with CYP2C19 and CYP3A4 inhibitors and inducers, and the related safe-use requirements using the ***Patient Brochure***
2. Assess the patient's cardiovascular status, including obtaining echocardiograms at the frequency described in the Prescribing Information:
    i. 4, 8, and 12 weeks after treatment initiation, then every 12 weeks thereafter
    ii. 4 weeks after interruption of treatment
    iii. 4 and 12 weeks after any dose change (including restart of treatment)
    iv. 4 and 12 weeks after initiating a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor
3. Assess the patient's current prescription and nonprescription medications and supplements for drug-drug interactions
4. Complete, sign, and submit a ***Patient Status Form*** to the CAMZYOS REMS, documenting that the patient has been counseled, the echocardiogram for the required time interval based on the Prescribing Information has been performed, assessment of drug-drug interactions has been performed, and it is appropriate for the patient to continue treatment
5. Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb at 833-628-7367

The CAMZYOS REMS will send reminders to the certified healthcare provider to submit the ***Patient Status Form***. Completed forms should be submitted to the CAMZYOS REMS online at **CAMZYOSREMS.com** or via fax to 833-299-9539.

Failure to submit the ***Patient Status Form*** at the required intervals could result in a delay in dispensing of CAMZYOS to the patient.

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Pharmacy Requirements

Only pharmacies certified in the CAMZYOS REMS can dispense CAMZYOS.

Become Certified

Before dispensing CAMZYOS:

1. Designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy
2. Have the authorized representative review the following educational materials:
   - Prescribing Information
   - ***Education Program for Healthcare Providers and Pharmacies***
   - ***Program Overview*** (this document)
3. Have the authorized representative successfully complete the ***Pharmacy Authorized Representative Knowledge Assessment*** and submit it to the REMS
4. Have the authorized representative enroll the pharmacy by completing the ***Pharmacy Enrollment Form*** and submitting it to the REMS
5. Train all relevant staff involved in dispensing CAMZYOS using the ***Program Overview*** and the ***Education Program for Healthcare Providers and Pharmacies***
6. Establish processes and procedures to comply with the CAMZYOS REMS

Ensure Compliance With the CAMZYOS REMS Requirements

When dispensing CAMZYOS:

1. Counsel the patient on drug-drug interactions
2. Assess the patient's prescription and nonprescription medications and supplements for drug-drug interactions. Document and submit to the REMS using the ***Drug Interaction and Counseling Checklist for Pharmacies***
3. Document the prescribed dose
4. Obtain authorization to dispense each prescription by contacting the REMS to verify that the:
   - Prescriber is certified and the patient is enrolled
   - Healthcare provider has authorized the patient to receive the drug, the patient was counseled, and the pharmacy identified and resolved any drug-drug interactions
5. Provide a ***Patient Brochure*** with each shipment of CAMZYOS
6. Dispense no more than a 35-day supply of CAMZYOS
7. If the authorized representative of the pharmacy changes, have the new representative enroll in the REMS by successfully completing the ***Pharmacy Authorized Representative Knowledge Assessment*** and completing the ***Pharmacy Enrollment Form***
8. Report adverse events of heart failure due to systolic dysfunction to Bristol Myers Squibb at 833-628-7367
9. Do not distribute, transfer, loan, or sell CAMZYOS, except to a certified pharmacy
10. Maintain records of dispensing information
11. Maintain records documenting completion of the REMS training by relevant staff
12. Maintain records that all processes and procedures are in place and are being followed
13. Comply with audits conducted by MyoKardia, Inc. or a third party acting on behalf of MyoKardia, Inc. to ensure that all processes and procedures are in place and are being followed

CAMZYOS is not available to all pharmacies. If you have questions about the CAMZYOS REMS or how to obtain CAMZYOS, call 833-628-7367.

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Patient Requirements
Only patients enrolled in the CAMZYOS REMS can receive CAMZYOS.

Become Enrolled

Before starting CAMZYOS:

1. Receive counseling from the healthcare provider, using the ***Patient Brochure***, on the:
    a. Risk of heart failure due to systolic dysfunction (when the heart is unable to pump enough blood to the body)
    b. Risk of drug-drug interactions and the need to inform healthcare providers of all prescription and over-the-counter medicines and supplements they take
2. Get an echocardiogram to check their heart
3. Enroll in the REMS by completing the ***Patient Enrollment Form*** with the healthcare provider. Enrollment information will be provided to the REMS

At All Times

After starting CAMZYOS:

1. Receive counseling from the healthcare provider on the:
    a. Risk of heart failure due to systolic dysfunction
    b. Risk of drug-drug interactions and the need to inform healthcare providers of all prescription and over-the-counter medicines and supplements they take
2. Get echocardiograms to check their heart
3. Inform their healthcare providers or seek other medical attention if there are new or worsening symptoms of heart failure
4. Inform their healthcare providers about their treatment with CAMZYOS
5. Inform their healthcare providers of all concomitant products, including over-the-counter medicines and supplements. Patients must be advised not to take medicines contraindicated with CAMZYOS
6. Review all prescription and over-the-counter medicines and supplements with their healthcare provider and pharmacist

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Resources

The resources listed below are available for download at **CAMZYOSREMS.com**.

Healthcare Provider	Pharmacy	Patient
• Prescribing Information • Program Overview • Education Program for Healthcare Providers and Pharmacies • Healthcare Provider Knowledge Assessment • Healthcare Provider Enrollment Form • Patient Status Form • Healthcare Provider Designee Enrollment Form	• Prescribing Information • Program Overview • Education Program for Healthcare Providers and Pharmacies • Pharmacy Authorized Representative Knowledge Assessment • Pharmacy Enrollment Form • Drug Interaction and Counseling Checklist for Pharmacies	• Medication Guide • Patient Brochure • Patient Enrollment Form

For more information about the CAMZYOS REMS, visit **CAMZYOSREMS.com** or call the CAMZYOS REMS at 833-628-7367.

Please see Important Safety Information, including **Boxed WARNING**, and US Full Prescribing Information for CAMZYOS here.

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