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

CAMZYOS® REMS
Healthcare Provider Knowledge Assessment

Instructions:

1. Complete and submit this **Healthcare Provider Knowledge Assessment** to the REMS:
   - ▶ Online at **CAMZYOSREMS.com**, or
   - ▶ Print and fax the form to the CAMZYOS REMS at 833-299-9539
2. To complete certification, enroll in the REMS by completing and submitting the **Healthcare Provider Enrollment Form**

Complete all required fields on this form to avoid a delay in the enrollment process. You will be notified by email of the status of your certification within 1 business day once the **Healthcare Provider Enrollment Form** has also been submitted.

Healthcare Provider Information (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Healthcare Provider NPI #:		
*Phone: Area Code/Telephone Number		*Fax: Area Code/Fax Number
*Email:		

For Questions 1–10, select the correct answer. All questions must be answered correctly.

Question 1

The risk being mitigated in the CAMZYOS REMS is:

- ○ **A.** Liver function test elevations (>3 times the upper limit of normal)
- ○ **B.** Neutropenia
- ○ **C.** Heart failure due to systolic dysfunction
- ○ **D.** Severe skin reactions

Question 2

Which of the following **is** an objective of the CAMZYOS REMS?

- ○ **A.** Monitor for detection of heart failure due to systolic dysfunction with periodic echocardiograms
- ○ **B.** Reduce liver toxicity caused by CAMZYOS
- ○ **C.** Screen for drug interactions prior to each dispense
- ○ **D.** Options A and B only
- ○ **E.** Options A and C only
- ○ **F.** None of the above

Question 3

What is the recommended starting dose of CAMZYOS for adults?

- ○ **A.** 2.5 mg once daily
- ○ **B.** 5 mg once daily (or 2.5 mg for patients on stable therapy with a moderate CYP2C19 inhibitor or a strong CYP3A4 inhibitor)
- ○ **C.** 10 mg every other day

For internal use only

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

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Question 4

Prior to and during treatment with CAMZYOS, each individual patient needs to receive counseling from their healthcare provider, using the **Patient Brochure**, on:

- ○ **A.** The risk of drug-drug interactions with CYP2C19 or CYP3A4 inhibitors and inducers
- ○ **B.** The risk of heart failure due to systolic dysfunction
- ○ **C.** How to recognize and respond to the symptoms of heart failure due to systolic dysfunction
- ○ **D.** The need to inform healthcare providers of all the prescription and nonprescription medications they take
- ○ **E.** The need for echocardiograms during treatment with CAMZYOS
- ○ **F.** All of the above

Question 5

Echocardiograms are required at each of the following time points while on CAMZYOS, **except**:

- ○ **A.** Prior to initiation of treatment
- ○ **B.** 4 weeks after initiation of treatment
- ○ **C.** 8 weeks after initiation of treatment
- ○ **D.** 12 weeks after initiation of treatment
- ○ **E.** Once per year starting in the second year
- ○ **F.** 4 weeks after a dose increase or decrease

Question 6

Patients can elect not to enroll in the REMS and still receive treatment with CAMZYOS.

○ **A.** TRUE ○ **B.** FALSE

Question 7

A prescription for CAMZYOS must be sent to a certified pharmacy to be dispensed. Pharmacies certified in the REMS can dispense CAMZYOS.

○ **A.** TRUE ○ **B.** FALSE

Question 8

If during treatment with CAMZYOS a patient has an LVEF <50%, the following step(s) should be followed:

- ○ **A.** Treatment should be interrupted for 4 weeks
- ○ **B.** Echocardiogram should be repeated after 4 weeks
- ○ **C.** Once LVEF is ≥50%, treatment may be reinitiated at the next lower dose level
- ○ **D.** All of the above

Question 9

In order for patients to continue treatment with CAMZYOS, the healthcare provider or designee is required to submit a **Patient Status Form** after each required echocardiogram.

○ **A.** TRUE ○ **B.** FALSE

Question 10

If a patient must begin to use a moderate to strong CYP3A4 or a weak to moderate CYP2C19 inhibitor during CAMZYOS therapy, what must occur?

- ○ **A.** CAMZYOS must be discontinued
- ○ **B.** The dose of CAMZYOS must be increased by one level
- ○ **C.** The moderate to strong CYP3A4 or weak to moderate CYP2C19 inhibitor must be discontinued
- ○ **D.** The dose of CAMZYOS must be decreased by one level

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