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# Camzyos® (active substance: mavacamten)

First authorisation in Switzerland: 25 April 2023

Hard capsules for the treatment of obstructive hypertrophic cardiomyopathy

## About the medicinal product

The medicinal product Camzyos, containing the active substance mavacamten, is used in adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve the ability to be active and minimise disease symptoms.

oHCM is a disease of the heart muscle (cardiomyopathy), in which the wall of the left ventricle in particular thickens. This reduces the left ventricle's ability to pump and obstructs the blood flow from the heart around the human body.

The severity of the disease is indicated by the degree of physical limitation according to categories developed by the New York Heart Association (NYHA). NYHA category II indicates slight limitation of physical activity, while category III indicates marked physical limitations.

The disease is currently incurable. A genetic predisposition is frequently present. Since this is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

## Mode of action

The active substance mavacamten contained in Camzyos is a cardiac myosin inhibitor. Myosin and actin are components of the heart muscle. They work together to generate contraction and relaxation of the heart muscle. In oHCM, the heart muscle contracts excessively (hypercontractility), the relaxation phases between contractions are impaired, and energy use increases.

Mavacamten binds to cardiac myosin, preventing actin coupling. In oHCM, mavacamten normalises the hypercontractility, extends the relaxation phases, and reduces energy use in the muscle cells. The physical limitations arising from oHCM therefore improve.

## Indication

Camzyos, containing the active substance mavacamten, is a prescription-only medicine. Camzyos is available in packages containing 28 capsules at doses of 2.5 mg, 5 mg, 10 mg and 15 mg.

Before the start of treatment, an echocardiogram (procedure for imaging heart function) is carried out to determine the left ventricular ejection fraction (LVEF). The LVEF provides information on the blood volume pumped into the body from the left ventricle during contractions. If the volume is too low, treatment must not be started.

The usual starting dose is 5 mg once daily. The dose is increased under strict controls. The maximum dose is 15 mg once daily. Capsules can be taken without food.

Women of childbearing age who take Camzyos must not become pregnant and must use adequate contraception.

## Efficacy

The efficacy of Camzyos was investigated over 30 weeks in an international clinical study with 251 patients with symptomatic oHCM. 123 patients received mavacamten, and 128 received a dummy drug (placebo). 73% of the patients were in NYHA category II, and the rest were in NYHA category III. The following parameters were measured as primary endpoints of the clinical study: Improvement in oxygen saturation of the blood and NYHA category achieved.

In the mavacamten group, 37% of patients achieved an improvement in the parameters, compared with 17% in the placebo group.

## Precautions, undesirable effects, & risks

Camzyos must not be used in those who are hypersensitive to the active substance or any of the excipients.

An echocardiogram to assess cardiac function must be performed before Camzyos is first taken and at regular intervals during treatment.

When taken at the same time as Camzyos, numerous other medicinal products can increase the concentration of mavacamten in the blood, causing side effects.

All precautions, risks, and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

## Why the medicinal product has been authorised

The clinical study found that patients with oHCM who took Camzyos over 30 weeks were able to benefit from the treatment. The standard drug and surgical standard treatments currently available cannot adequately treat the underlying disease mechanisms of oHCM. There is therefore a medical need for an additional treatment option.

Taking all the risks and precautions into account, and based on the available data, the benefits of Camzyos outweigh the risks. Swissmedic has therefore authorised the medicinal product Camzyos, containing the active substance mavacamten, for use in Switzerland.

## Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Camzyos®

Information for patients (package leaflet): Information for patients Camzyos ®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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