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Camzyos (*mavacamten*)

An overview of Camzyos and why it is authorised in the EU

What is Camzyos and what is it used for?

Camzyos is a medicine used in adults to treat obstructive hypertrophic cardiomyopathy (oHCM), a disease in which the muscle in the main pumping chamber of the heart becomes thickened or enlarged, which can block the flow of blood from the heart to the rest of the body.

It is used in adults who have symptoms of the disease (class II or class III oHCM). The 'class' reflects the seriousness of the disease: 'class II' involves slight limitation of physical activity and 'class III' involves marked limitation of physical activity.

Camzyos contains the active substance mavacamten.

How is Camzyos used?

Camzyos can only be obtained with a prescription and treatment should be started under the supervision of a doctor with experience in treating cardiomyopathy (damage to the heart muscle).

Camzyos is available as a capsule, taken by mouth once daily. The dose depends on the activity of a liver enzyme, CYP2C19, which is involved in the breakdown of Camzyos and the patient's response to treatment.

Before starting treatment, the doctor will carry out a test to measure the activity of CYP2C19 to determine how quickly Camzyos is broken down by individual patients. If the activity of this liver enzyme is low, then the risk of getting serious side effects with Camzyos is greater and the doctor will prescribe a lower dose. If treatment has to be started before the test is carried out, the doctor will also prescribe a lower dose.

The doctor will also carry out tests, including an echocardiogram (a diagnostic test where an image of the heart is obtained using ultrasound), to check the patient's left ventricular ejection fraction (LVEF; the amount of blood pumped out of the heart by the lower left chamber in one beat). This will be done before starting treatment to decide whether Camzyos is suitable and at regular intervals during treatment to ensure the optimal dose.

Before starting treatment in women who can have children, the doctor will also carry out a pregnancy test to ensure that they are not pregnant.



For more information about using Camzyos, see the package leaflet or contact your doctor or pharmacist.

How does Camzyos work?

The heart pumps blood around the body when its muscles contract and relax. During a contraction protein filaments of myosin slide along actin filaments to shorten the muscle fibres. In oHCM, myosin and actin form excess connections, which causes the heart muscle to contract too much. Mavacamten, the active substance in Camzyos, binds to myosin, preventing it from attaching to actin, which reduces the excessive connections between these two proteins. This allows the heart muscle to relax more, thereby improving the symptoms of oHCM.

What benefits of Camzyos have been shown in studies?

The effectiveness of Camzyos was compared with placebo (a dummy treatment) in two main studies. The main measure of effectiveness in the first study, involving 251 patients with oHCM, was the proportion of patients who achieved a pre-defined level of improvement in both exercise capacity (measured by the maximum volume of oxygen used during exercise) together with an improvement or stabilisation in symptoms of the disease. After 30 weeks of treatment, 37% of patients treated with Camzyos achieved this improvement compared with 17% of those treated with placebo.

The second study involved 112 patients with oHCM who were eligible for septal reduction therapy (SRT), where the size of the thickened heart muscle is reduced through surgery or a procedure using a catheter (a thin tube passed through an artery into the heart). After 16 weeks of treatment with Camzyos, 18% of patients proceeded with SRT or were still eligible for SRT compared with 77% of those who received placebo.

What are the risks associated with Camzyos?

For the full list of side effects and restrictions with Camzyos, see the package leaflet.

The most common side effects with Camzyos (which may affect up to 2 in 10 people) include dizziness, dyspnoea (difficulty breathing), systolic dysfunction (a condition where the heart cannot pump with enough force) and syncope (fainting).

Camzyos must not be taken during pregnancy or by women who can become pregnant and who are not using appropriate contraceptives. It must also not be taken with a number of other medicines which may increase the amount of Camzyos in the patient's body, thereby increasing the risk of side effects.

Why is Camzyos authorised in the EU?

At the time of authorisation of Camzyos, there were no other medicines that treat the underlying abnormal heart function which causes oHCM. Management of the disease is restricted to treatments which improve symptoms or surgical procedures. Camzyos, is a targeted therapy for the disease which has been shown to provide clinically relevant improvements in patients with oHCM. While the side effects of Camzyos are considered manageable, the studies to evaluate its safety had a limited number of patients. Therefore, further studies and analysis are ongoing to evaluate the risk of side effects with Camzyos, particularly those which affect the heart.

The European Medicines Agency decided that Camzyos' benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Camzyos?

The company that markets Camzyos will provide a patient card containing important safety information, including the need to avoid pregnancy during treatment, as well as instructions on when to contact the doctor if patients have new or worsening symptoms of heart failure. The alert card also contains information on the risk of interaction with other medicines. A checklist will also be provided to healthcare professionals regarding the risks associated with Camzyos and how these should be managed.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Camzyos have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Camzyos are continuously monitored. Suspected side effects reported with Camzyos are carefully evaluated and any necessary action taken to protect patients.

Other information about Camzyos

Camzyos received a marketing authorisation valid throughout the EU on 26 June 2023.

Further information on Camzyos can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/camzyos

This overview was last updated in 06-2023.