Package leaflet: Information for the patient

MYQORZO 5 mg film-coated tablets
MYQORZO 10 mg film-coated tablets
MYQORZO 15 mg film-coated tablets
MYQORZO 20 mg film-coated tablets
aficamten

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- You will receive a **Patient Card**. Read it carefully and follow the instructions.
- Always show the Patient Card to the doctor, pharmacist, or nurse when you see them or if you go to the hospital.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What MYQORZO is and what it is used for

MYQORZO contains the active substance aficamten. Aficamten is a reversible cardiac myosin inhibitor, meaning that it changes the action of the muscle protein myosin in heart muscle cells.

MYQORZO is used to treat adults with a type of heart disease called obstructive hypertrophic cardiomyopathy (oHCM). 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.

Hypertrophic cardiomyopathy (HCM) is a condition where the walls of the left heart chamber (ventricle) contract harder and become thicker than normal. As the walls thicken they can block (obstruct) the flow of blood leaving the heart and can also make the heart muscle stiff. This blockage (obstruction) makes it harder for blood to enter and exit the heart, reducing its ability to pump blood to the rest of the body. This condition is known as obstructive hypertrophic cardiomyopathy (oHCM). Symptoms of oHCM include chest pain and shortness of breath (especially with physical exercise), tiredness, abnormal heart rhythms, dizziness, feeling you are about to faint, fainting (syncope) and swelling of the ankles, feet, legs, abdomen and/or veins in the neck.

The active substance in MYQORZO, aficamten, binds to the protein myosin in the heart muscle. This reduces the excess contraction of the heart which helps the heart pump more smoothly, reduces the blockage in blood flow and may improve symptoms of oHCM.

2. What you need to know before you take MYQORZO

Do not take MYQORZO:
- if you are allergic to aficamten or any of the other ingredients of this medicine (listed in section 6).
- If you are taking the following medicines:
  - fluconazole for more than 1 dose (a medicine commonly used to treat fungal infections).
  - adagrasib (a medicine used for the treatment of certain cancers).
  - rifampicin (an antibiotic for infections like tuberculosis).
  - St. John's wort (an herbal supplement for depression).

Ask your doctor if the medicine you are taking prevents you from taking aficamten. See section 'Other medicines and MYQORZO'.

Do not take MYQORZO if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking MYQORZO.

Warnings and precautions
Talk to your doctor before taking MYQORZO.

Tell your doctor or pharmacist immediately if you get any of these symptoms (new or worsening) during your treatment with MYQORZO:
- irregular heartbeats (arrhythmia)
- shortness of breath (dyspnoea)
- chest pain
- tiredness or
- leg swelling.

These could be signs and symptoms of systolic dysfunction, a condition where the heart cannot pump with enough force, which can be life-threatening and lead to heart failure (see section 4).

Tell your doctor or pharmacist immediately if you develop a serious infection or new or worsening irregular heartbeat (arrhythmia) as this could increase your risk of developing systolic dysfunction and heart failure. Your doctor may need to do additional tests to evaluate how well your heart is functioning.

Routine tests
Your doctor will assess how well your heart is working (your heart function) using an echocardiogram (an ultrasound test that takes images of your heart) to check your 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 your first dose and regularly during treatment with MYQORZO. It is very important to have these echocardiogram appointments, because your doctor needs to check the effect of MYQORZO on your heart. Your treatment dose may need to be adjusted to improve your response or to reduce side effects.

Children and adolescents
Do not give this medicine to children and adolescents (aged below 18 years) because the effectiveness and safety of MYQORZO have not been studied in this age group.

Other medicines and MYQORZO
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because some other medicines can affect the way MYQORZO works. Some medicines can increase the amount of MYQORZO in your body and make it more likely for you to get side effects that may be severe. Other medicines can reduce the amount of MYQORZO in your body and may reduce its beneficial effects.

Do not take MYQORZO if you are taking any of the following:
- more than 1 dose of fluconazole (a medicine used to treat fungal infections)
- adagrasib (a medicine used to treat certain types of cancer)

- rifampicin (an antibiotic for infections like tuberculosis)
- St. John's wort (an herbal supplement for depression)

Before taking MYQORZO tell your doctor or pharmacist if you are taking, have recently taken, or have changed the dose of any of the following medicines:
- Some medicines used to treat fungal infections, for example voriconazole
- Medicines used to treat certain anxiety disorders, for example fluvoxamine, fluoxetine
- Some medicines used to treat bacterial infections, for example sulfaphenazole
- Medicines used to treat cancer, such as apalutamide, enzalutamide, mitotane
- Some medicines used to treat seizures, for example carbamazepine, phenytoin

If you take or have taken any of these medicines, or have changed the dose, your doctor needs to closely monitor you, may need to change your dose of MYQORZO, or consider alternative treatments.

If you are not sure whether you are taking any of the medicines mentioned above, ask your doctor or pharmacist before taking MYQORZO.

Before stopping or changing the dose of a medicine or starting a new medicine, tell your doctor or pharmacist.

Do not take any of the above medicines occasionally or once in a while (not on a regular schedule) since that could change the amount of MYQORZO in your body.

Pregnancy
Women of childbearing potential have to use effective contraception during treatment.

There is no experience of using MYQORZO in pregnant women. It is uncertain if MYQORZO could cause harm to your unborn baby. You should not use this medicine while pregnant unless your doctor evaluates your condition and prescribes it for you. If you are pregnant, think you may be pregnant or are planning to become pregnant tell your doctor immediately. Your doctor will discuss with you the potential risks of taking MYQORZO during pregnancy and decide if the treatment should be started or continued. If you are treated with MYQORZO during pregnancy, your doctor will carefully monitor you and your baby's heart function by doing echocardiograms. If there is a change in you or your baby's heart function, your doctor may adjust your dose or stop the treatment.

Breast-feeding
If you plan to breast feed, ask your doctor or pharmacist for advice before taking this medicine. This is because it is not known whether the medicine passes into human breast milk or what the effects might be on the baby.

Driving and using machines
MYQORZO may have a small effect on your ability to drive and use machines. If you feel dizzy while taking this medicine, do not drive a vehicle, cycle or use any tools or machines (see section 4 'Possible side effects').

MYQORZO contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take MYQORZO

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Treatment with MYQORZO should be started under the supervision of a doctor experienced in the management of patients with cardiomyopathy.

Your doctor will prescribe you a single daily dose of either 5 mg, 10 mg, 15 mg or 20 mg. The maximum single dose is 20 mg once daily.

The recommended starting dose is one 5 mg film-coated tablet taken by mouth once a day. After you start treatment, your doctor will increase your dose by 5 mg every 2 to 8 weeks until a regular daily (maintenance) dose or the maximum daily dose is reached.

Your doctor will tell you how much MYQORZO to take.

Echocardiograms
While you are taking MYQORZO, your doctor will monitor how well your heart is working using echocardiograms and may adjust your dose based on the results of your echocardiogram (increase or lower your dose or temporarily stop treatment).

Your first echocardiogram will be done before you start treatment, and then again during follow-up visits every 2 to 8 weeks to assess how you are responding to MYQORZO. If your doctor changes your dose of MYQORZO at any point, an echocardiogram will be performed within 8 weeks afterwards to make sure you are receiving the correct dose (see section 2, Routine tests). When you have reached a regular daily (maintenance) dose, echocardiograms will be done every 3 months or 6 months.

Taking this medicine
Swallow the tablet whole with a glass of water each day. Do not split, crush, or chew the tablet. You can take this medicine with or without food.

If you take more MYQORZO than you should
If you take more tablets than you should, contact your doctor or go to a hospital immediately. If possible, take the medicine pack and this leaflet with you.

If you forget to take MYQORZO
If you forget to take MYQORZO at the usual time, take your dose as soon as you remember on the same day and take your next dose the next day. Do not take a double dose to make up for a forgotten tablet.

If you stop taking MYQORZO
Do not stop taking MYQORZO unless your doctor tells you to. If you stop taking MYQORZO, your HCM symptoms may return. If you wish to stop taking MYQORZO, notify your doctor to discuss the best way to do so.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with MYQORZO:

Common (may affect up to 1 in 10 people)
- dizziness
- new or worsening shortness of breath, chest pain, tiredness, or leg swelling. These could be signs and symptoms of systolic dysfunction (a condition where the heart cannot pump with enough force), which can lead to heart failure and be life-threatening.
- feeling your heartbeat.
- increase in blood pressure.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MYQORZO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister pack after 'EXP'. The expiry date refers to the last day of that month.

Store below 30 °C.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What MYQORZO contains

- The active substance is aficamten. Each film-coated tablet (tablet) contains 5 mg, 10 mg, 15 mg or 20 mg aficamten.

- The other ingredients are:
  - Tablet core: Microcrystalline cellulose (E 460i), mannitol (E 421), croscarmellose sodium (E 468), hydroxypropylcellulose (E 463), sodium laurilsulfate, magnesium stearate (E 470b). See section 2 'MYQORZO contains sodium'.
  - Tablet film coating: Macrogol poly(vinyl alcohol) grafted copolymer (E 1209), talc (E 553b), titanium dioxide (E 171), glycerol mono and dicaprylocaprate (E 471), poly(vinyl alcohol) (E 1203), indigo carmine aluminium lake (E 132), carmine (E 120).

What MYQORZO looks like and contents of the pack

- MYQORZO 5 mg film-coated tablets are purple, round tablets debossed with "5" on one side and "CK" on the other side. Tablet size of approximately 4.84 mm in diameter.
- MYQORZO 10 mg film-coated tablets are purple, triangle tablets debossed with "10" on one side and "CK" on the other side. Tablet size of approximately 6.73 mm x 6.99 mm.
- MYQORZO 15 mg film-coated tablets are purple, pentagon tablets debossed with "15" on one side and "CK" on the other side. Tablet size of approximately 7.33 mm x 7.37 mm.
- MYQORZO 20 mg film-coated tablets are purple, oval tablets debossed with "20" on one side and "CK" on the other side. Tablet size of approximately 5.46 mm x 10.29 mm.

The tablets are available in aluminium foil blisters containing 14 film-coated tablets.

Each pack contains 14, 28, or 98 tablets. Not all pack sizes may be marketed.

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