11 December 2025
EMA/376438/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Myqorzo

aficamten

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Myqorzo, intended for the treatment of adults with obstructive hypertrophic cardiomyopathy (oHCM).

The applicant for this medicinal product is Cytokinetics (Ireland) Limited.

Myqorzo will be available as 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets. The active substance of Myqorzo is aficamten, a reversible cardiac myosin inhibitor (ATC code: not yet assigned). Aficamten binds directly to the motor domain of cardiac myosin and prevents it from entering the force-producing state. This lowers cardiac contractility, leading to reduced left ventricular outflow tract obstruction in patients with hypertrophic cardiomyopathy.

The benefits of Myqorzo, as shown in a phase 3 randomised, placebo-controlled trial, are an improvement in exercise capacity (as measured by pVO_2max) and a reduced need for septal reduction therapy in patients with oHCM who received aficamten compared with placebo. The most common side effects with Myqorzo are dizziness, systolic dysfunction defined as left ventricular ejection fraction below 50%, palpitations and hypertension.

The full indication is:

> MYQORZO is indicated for the treatment of symptomatic (New York Heart Association, NYHA, class II-III) obstructive hypertrophic cardiomyopathy (oHCM) in adult patients (see section 5.1).

Treatment with Myqorzo should be initiated by physicians experienced in the management of patients with cardiomyopathy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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