20 May 2021
EMA/CHMP/259029/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Verquvo

vericiguat

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Verquvo, intended for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction.

The applicant for this medicinal product is Bayer AG.

Verquvo will be available as 2.5-mg, 5-mg and 10-mg film-coated tablets. The active substance of Verquvo is vericiguat (ATC code: C01DX22).

Vericiguat stimulates directly soluble guanylate cyclase (sGC), independently of and synergistically with nitric oxide (NO), to augment the levels of intracellular cGMP. This leads to smooth muscle relaxation and vasodilation, which may improve both myocardial and vascular function.

The benefits of Verquvo are its ability to reduce the risk of cardiovascular death or hospitalisation due to heart failure in patients with chronic heart failure and reduced ejection fraction who are stabilised after a recent decompensation event. The most common side effects are hypotension, dizziness, nausea, orthostatic hypotension, dyspepsia and gastroesophageal reflux disease.

The full indication is:

> Verquvo is indicated for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilised after a recent decompensation event requiring IV therapy (see section 5.1).

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union