27 June 2019
EMA/CHMP/287624/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Giapreza

angiotensin II

On 27 June 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Giapreza, intended for the treatment of refractory hypotension in adults with septic or other distributive shock. The applicant for this medicinal product is La Jolla Pharmaceutical II B.V.

Giapreza will be available as a 2.5 mg/ml concentrate for solution for infusion. The active substance in Giapreza is angiotensin II acetate, which raises blood pressure by vasoconstriction (ATC code: C01CX009).

The benefit with Giapreza is its ability to increase blood pressure in patients with septic and distributive shock. The most common side effects are thromboembolic events, transient hypertension, tachycardia and peripheral ischaemia.

The full indication is: "Giapreza is indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies (see section 5.1)". It is proposed that Giapreza be prescribed by physicians experienced in the treatment of shock and used in an acute and hospital setting.

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