EMA/370784/2019
EMEA/H/C/004930

Giapreza (*angiotensin II*)

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

What is Giapreza and what is it used for?

Giapreza is a medicine used in adults with dangerously low blood pressure (a condition known as shock).

It is used when other treatments for raising blood pressure have not worked and contains the active substance angiotensin II.

How is Giapreza used?

The medicine should be prescribed by a physician experienced in the treatment of shock and is for use in a hospital setting. It is given as a continuous infusion ('drip') into a vein. The dose depends on the patient's weight and should be adjusted according to the patient's blood pressure.

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

How does Giapreza work?

The active substance in Giapreza, angiotensin II, is the same as a hormone that the body produces. Angiotensin II increases blood pressure by narrowing blood vessels and releasing another hormone (aldosterone) that increases the volume of blood circulating in the body.

What benefits of Giapreza have been shown in studies?

A main study involving 344 patients in shock has shown that Giapreza is effective at raising blood pressure when other treatments have not worked. After 3 hours, 70% of patients treated with Giapreza in addition to standard treatments had their average arterial blood pressure rise to above 75 mmHg (an acceptable level) or by at least 10 mmHg, compared with 23% of patients treated with placebo (a dummy treatment) and standard treatments.

What are the risks associated with Giapreza?

The most common side effects with Giapreza (which may affect more than 1 in 10 people) are thromboembolic events (problems due to clots in blood vessels) and short-lived high blood pressure.

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

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

Why is Giapreza authorised in the EU?

The main study showed that adding Giapreza to standard treatment was effective in increasing average blood pressure in patients in shock. The rise in blood pressure is expected to help prevent organ damage and reduce the number of deaths from this condition. The side effects of Giapreza were similar to those of standard treatments and were considered manageable. The European Medicines Agency therefore decided that Giapreza's benefits are greater than its risks and that it can be authorised for use in the EU.

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

The company that markets Giapreza will carry out a study to further investigate the effectiveness and safety of Giapreza, including whether the medicine could prevent damage to organs and affect how long patients live.

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

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

Other information about Giapreza

Giapreza received a marketing authorisation valid throughout the EU on 23 August 2019.

Further information on Giapreza can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/giapreza

This overview was last updated in 08-2019.