

Package leaflet: Information for the patient

Giapreza 2.5 mg/ml concentrate for solution for infusion angiotensin II

▼ 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 are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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 Giapreza is and what it is used for
2. What you need to know before you are given Giapreza
3. How Giapreza is used
4. Possible side effects
5. How Giapreza is stored
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1. What Giapreza is and what it is used for

Giapreza contains the active substance angiotensin II, a compound normally produced by the body. It makes the blood vessels tighten and become narrower, thus increasing blood pressure.

Giapreza is used in an emergency setting to increase blood pressure to normal levels in adult patients with seriously low blood pressure who do not respond to fluids or other medicines that raise blood pressure.

2. What you need to know before you are given Giapreza

You must not be given Giapreza:

- if you are allergic to angiotensin II or any of the other ingredients of this medicine (listed in section 6).

Your doctor or nurse should be told if any of the above applies to you before this medicine is used.

Warnings and precautions

Giapreza has only been tested in people with septic and distributive shock. It has not been tested in other types of shock.

This medicine has been associated with the formation of blood clots. As a part of your treatment, you will be given medicine to prevent the formation of blood clots unless your doctor considers it inappropriate.

When you are first given Giapreza, it is expected that your blood pressure will increase. You will be monitored closely to make sure that your blood pressure is at the right level.

Tell your doctor or nurse immediately if you experience a change of colour (redness or paleness), pain, numbness in any of your limbs, or if any of your limbs are cold to the touch, as these could be signs that a blood clot has blocked blood flow to a part of the body.

Children and adolescents

Giapreza should not be used in children or adolescents under 18 years of age as it has not been studied in these age groups.

Other medicines and Giapreza

Your doctor should be told if you are using, have recently used, or might use any other medicines.

A number of medicines may affect the way Giapreza works, such as:

- Angiotensin converting enzyme (ACE) inhibitors like enalapril (medicines used to lower blood pressure). ACE inhibitors may increase to the effect of Giapreza.
- Angiotensin II receptor blockers like candesartan (medicines used to lower blood pressure) may lessen the effect of Giapreza.

Your doctor may already be giving you other medicines used to increase your blood pressure. Adding Giapreza to these medicines may require that the doses of the other medicines be lowered.

Pregnancy, breast-feeding and fertility

Your doctor should be told if you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby before this medicine is given.

There is limited information about the effects of Giapreza during pregnancy. Use of this medicine during pregnancy should be avoided if possible. Your doctor will give you this medicine only if the possible benefit is greater than the possible risks.

It is not known whether Giapreza can pass into breast milk. Your doctor should be told if you are breast-feeding before this medicine is given.

Breastfeeding should be discontinued during treatment.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per 2.5 mg/1 ml, that is to say essentially 'sodium-free'.

3. How Giapreza is used

Giapreza will be given to you in a hospital by a doctor or a nurse. It is first diluted and then given as a drip (infusion) into a vein, supplying a specified dose each minute.

The dose depends on your body weight. The recommended starting rate of Giapreza is 20 nanograms (ng) per kilogram of your body weight per minute. After the initial dose, your doctor will adjust the rate as often as every 5 minutes until you achieve your target blood pressure. Your doctor will continue to assess your response and will adjust the dose accordingly up to a maximum of 80 ng per kilogram each minute during the first 3 hours of treatment. The maximum dose after the first 3 hours will be 40 ng per kilogram each minute.

Giapreza will be given to you at the lowest dose that helps you to achieve or maintain your blood pressure. In order to minimise the risk of side effects to this medicine, Giapreza will be withdrawn as soon as your condition improves.

Elderly

Giapreza was tested in a small number of patients more than 75 years of age. There are no dose adjustments needed for patients more than 75 years of age. Your doctor will monitor your blood pressure and adjust your dose as needed.

Impairment of liver or kidneys

There are no dose adjustments needed for patients with impairment of the function of the liver or kidneys. Your doctor will monitor your blood pressure and adjust your dose as needed.

If you are given more Giapreza than you should

Giapreza will be given to you by a doctor or a nurse, so it is unlikely you will be given the wrong dose. However, if you have side effects or think you have been given too much Giapreza, tell your doctor or nurse straight away. If you have too much Giapreza, you may experience high blood pressure. If this occurs, hospital staff will monitor your vital signs and you will be provided with supportive care.

Stopping Giapreza treatment

Your doctor will gradually decrease the amount of Giapreza you are given over time once your blood pressure has increased to appropriate levels. If Giapreza is stopped suddenly or stopped too early, you may experience a decrease in your blood pressure or your condition may worsen.

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

4. Possible side effects

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

Tell your doctor immediately if you experience:

- Pain, redness or pale colour, swelling or coolness to the touch of the skin or limbs, as these may be symptoms of a blood clot in one of your veins. These clots may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms, seek medical advice immediately. These types of symptoms occur in greater than 1 out of every 10 patients. While not all of these symptoms lead to life-threatening complications, your doctor should be told about them immediately.

Other side effects are:

Very common side effects (may affect more than 1 in 10 people) are:

- Too high blood pressure

Common side effects (may affect up to 1 in 10 people) are:

- Rapid heartbeat
- Poor circulation to your hands, feet, or other bodily areas which can be severe and cause tissue damage.

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, website: <http://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 Giapreza

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 carton and vial after “EXP”. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C).

The diluted solution should be used immediately. Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature and 2 °C - 8 °C.

Do not use if you notice any signs of visible damage or discolouration.

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

6. Contents of the pack and other information

What Giapreza contains

- The active substance is angiotensin II acetate. Each ml contains angiotensin II acetate equivalent to 2.5 mg angiotensin II.
 - One vial of 1 ml concentrate for solution for infusion contains 2.5 mg of angiotensin II
 - One vial of 2 ml concentrate for solution for infusion contains 5 mg of angiotensin II
- The other ingredients are mannitol and water for injections, pH adjusted with sodium hydroxide and/or hydrochloric acid (see section 2 under ‘Sodium’).

What Giapreza looks like and contents of the pack

Giapreza 2.5 mg/ml is presented as a concentrate for solution for infusion (sterile concentrate). The solution is a clear, colourless solution free of any visible particles.

Giapreza is supplied in a carton containing either 1 × 1 ml, 10 x 1 ml or 1 x 2 ml single use vial. Not all pack sizes may be marketed.

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