

Package leaflet: Information for the patient

Ruconest 2100 U powder for solution for injection Conestat alfa

Read all of this leaflet carefully before you start using 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Ruconest is and what it is used for
2. What you need to know before you use Ruconest
3. How to use Ruconest
4. Possible side effects
5. How to store Ruconest
6. Contents of the pack and other information

1. What Ruconest is and what it is used for

Ruconest contains conestat alfa as the active substance. Conestat alfa is a **recombinant form of human C1 inhibitor (rhC1INH)** and is produced using recombinant DNA technology from the milk of rabbits.

Ruconest is to be used by adults with a rare inherited blood disorder, called Hereditary Angioedema (HAE). These patients have a shortage of the C1 inhibitor protein in their blood. This can lead to repeated attacks of swelling, pain in the abdomen, difficulty breathing and other symptoms.

The administration of conestat alfa (Ruconest) is to resolve the shortage of C1 inhibitor and will lead to reduction of symptoms of an acute attack of HAE.

2. What you need to know before you use Ruconest

Do not use Ruconest:

- If you are or think you are allergic to rabbits
- If you are allergic to conestat alfa or any of the other ingredients of this medicine (listed in section 6).

Only use Ruconest if you have a negative test for rabbit allergy (IgE). Repeat this test every year or after every 10 treatments with Ruconest, whichever occurs first.

Warnings and precautions

Talk to your doctor before using Ruconest.

If you experience allergic reactions e.g. hives, rash, itching, dizziness, wheezing, difficulty breathing or your tongue swells up following the administration of Ruconest, you should seek emergency medical assistance so that symptoms of your allergic reaction can be treated urgently.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years old.

Other medicines and Ruconest

Tell your doctor if you are taking, have recently taken or might take any other medicines.
If you are receiving acute treatment for blood clots, you should not be treated with Ruconest at the same time.

Pregnancy and breast-feeding

It is not recommended to use Ruconest during pregnancy or breast-feeding.
If you plan becoming pregnant, discuss with your doctor before starting to use Ruconest.

Driving and using machines

Do not drive or use machinery if you feel dizzy or suffer from headache after using Ruconest.

3. How to use Ruconest

Ruconest will be given to you directly into a vein over a period of approximately 5 minutes by your doctor or by a nurse. Your dose will be worked out based on your weight.
Most of the time a single dose is sufficient, but a second dose may be needed. No more than 2 doses should be given within 24 hours.

The instructions for use are clearly described in the doctor's information leaflet and are attached.

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.

If your symptoms get worse and/or you develop a rash, tingling, difficulty breathing or your face or tongue swells up, get medical attention **immediately**.

This may indicate that you have developed an allergy to Ruconest.

Some side effects may occur during treatment with Ruconest:

Common (affect 1 to 10 users in 100):
headache

Uncommon (affect 1 to 10 users in 1,000):
sensation of tingling, prickling or numbness in the skin or limb (paraesthesia), dizziness, throat irritation, abdominal pain, diarrhoea, nausea, hives and swelling of the skin.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in the leaflet.

5. How to store Ruconest

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 on the label of the vial after EXP. The expiry date refers to the last day of that month

Do not store above 25°C.

Store in the original package in order to protect from light.

Before Ruconest can be administered, it needs to be dissolved in water for injections, by a healthcare professional.

Once reconstituted, the product should be used immediately.

Do not use this medicine if you notice particles in the solution or if the solution is discolored.

6. Contents of the pack and other information

What Ruconest contains

The active substance is conestat alfa. Each vial contains 2100 units of conestat alfa, corresponding to 2100 units per 14 ml after reconstitution, or a concentration of 150 units/ml.

The other ingredients are sucrose, sodium citrate (E331) and citric acid (E330).

What Ruconest looks like and contents of the pack

Ruconest is presented as a single glass vial containing a white to off-white powder for solution for injection. After dissolving the powder in water for injections, the solution is clear and colourless. Ruconest is supplied in a carton box containing one vial.

Marketing Authorisation Holder and Manufacturer

Pharming Group N.V.
Darwinweg 24
NL-2333 CR Leiden
The Netherlands

This leaflet was last revised in 2013-09-25

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.



The following information is intended for medical or healthcare professionals only:

POSODOLOGY AND METHOD OF ADMINISTRATION

- Adults up to 84 kg body weight

One intravenous injection of 50 U/kg body weight.

- Adults of 84 kg body weight or greater

One intravenous injection of 4200 U (two vials).

In the majority of cases a single dose of Ruconest is sufficient to treat an acute angioedema attack.

In case of an insufficient clinical response, an additional dose (50 U/kg body weight up to 4200 U) can be administered.

Not more than two doses should be administered within 24 hours.

Dose calculation

Determine the patient's body weight.

- *Adults up to 84 kg body weight*

For patients up to 84 kg calculate the volume required to be administered according to the formula below:

$$\text{Volume to be administered (ml)} = \frac{\text{body weight (kg) times 50 (U/kg)}}{150 \text{ (U/ml)}} = \frac{\text{body weight (kg)}}{3}$$

- *Adults of 84 kg body weight or greater*

For patients of 84 kg or above the volume required to be administered is 28 ml, corresponding to 4200 U (2 vials).

Reconstitute *each vial* with 14 ml water for injections (see section on Reconstitution below).

The reconstituted solution in each vial contains 2100 U conestat alfa at 150 U/ml.

The required volume of the reconstituted solution should be administered as a slow intravenous injection over approximately 5 minutes.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Each vial of Ruconest is for single use only.

An aseptic technique should be used for reconstitution, combining and mixing the solutions.

Reconstitution

Each vial of Ruconest (2100 U) should be reconstituted with 14 ml water for injections. Water for injections should be added slowly to avoid forceful impact on the powder and mixed gently to avoid foaming of the solution. The reconstituted solution in each vial contains 2100 U conestat alfa at 150 U/ml and appears as a clear colourless solution.

The reconstituted solution in each vial should be inspected for particulate matter and discoloration. A solution exhibiting particulates or discoloration should not be used. The medicinal product should be used immediately.

No special requirements for disposal.