A. PACKAGE LEAFLET

Package leaflet: Information for the patient

Ruconest 2100 Units 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. See section 4.

What is in this leaflet

1. What Ruconest is and what it is used for

Ruconest contains conestat alfa as the active substance. Conestat alfa is a recombinant (not blood-derived) form of human C1 inhibitor (rhC1-INH).

Ruconest is to be used by adults, adolescents, and children (aged 2 years and above) 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 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).

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.

Before you start treatment with Ruconest, it is important that you tell your doctor if you have, or have had, problems with your blood clotting (thrombotic events). You will be carefully monitored if this is the case.

Hypersensitivity reactions cannot be excluded and may have symptoms similar to angioedema attacks.

Children and adolescents
Do not give this medicine to children under 2 years old. Ruconest has not been studied in children younger than 5 years of age. Your doctor will determine whether treatment of your child with Ruconest is appropriate. Additional monitoring of your child for symptoms of allergic reactions during and after administration is needed.

Other medicines and Ruconest
Tell your doctor if you are taking, have recently taken or might take any other medicines.
If you are receiving tissue type plasminogen activator as 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.

Ruconest contains sodium (19.5 mg per vial)
This should be taken into consideration by patients on a controlled sodium diet.

3. How to use Ruconest

Ruconest will be initiated by a doctor who is specialised in the diagnosis and treatment of hereditary angioedema.

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, up to 2 vials, will be worked out based on your weight.

Most of the time a single dose is sufficient. Your doctor may decide that an additional dose should be administered if your symptoms do not improve after 120 minutes (for adults and adolescents) or 60 minutes (for children). 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: may affect up to 1 in 10 people
- Nausea

Uncommon: may affect up to 1 in 100 people
- Abdominal pain, diarrhoea
- Sensation of tingling, prickling or numbness in the mouth
- Headache, dizziness
- Reduced sense of touch or sensation in skin or limbs
- Throat irritation
- Hives

- Swelling of the ears or the area around the ears
- Allergic shock

Not known: the frequency is not known
- Hypersensitivity reactions

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

For any patients who do not have online access to report a suspected side effect to the Yellow Card scheme, call 0800 731 6789 for free, Monday to Friday between 10am and 2pm.

By reporting side effects you can help provide more information on the safety of this medicine.

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 discoloured.

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.

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

Marketing Authorisation Holder:
Pharming Group N.V.

Darwinweg 24
2333 CR Leiden
The Netherlands

Manufacturer:
Pharming Technologies B.V.
Darwinweg 24
2333 CR Leiden
The Netherlands

This leaflet was last revised in July 2023.

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

The following information is intended for healthcare professionals only:

POSOLOGY AND METHOD OF ADMINISTRATION

Posology
Body weight up to 84 kg
- One intravenous injection of 50 U/kg body weight.

Body weight of 84 kg 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.
Body weight up to 84 kg
- For patients up to 84 kg calculate the volume required to be administered according to the formula below:

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

Body weight of 84 kg 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 minimise 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.