PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

RUCONEST

powder for solution for injection
2100 Units

The active ingredients and their quantities:
Each vial contains conestat alfa 2100 units, corresponding to 2100 units per 14 ml after reconstitution, or a concentration of 150 units/ml.
Inactive ingredients and allergens in the product: see in section 2 "Important information about some of the ingredients of the medicine" and see also section 6 "Additional Information".
Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you/to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment/medical condition is similar.
The medicine is not indicated for children less than 12 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ruconest is indicated for treatment of acute angioedema attacks in adults and adolescents aged 12 years and above with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.
Therapeutic group: recombinant (not blood-derived) form of human C1 inhibitor (rhC1-INH), drugs used in hereditary angioedema.
Patients with a rare inherited blood disorder, called Hereditary Angioedema (HAE), 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. BEFORE USING THE MEDICINE

Do not use the medicine 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).

Special warnings regarding use of the medicine
Before using Ruconest, inform the doctor if:
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
Ruconest should not be given to children less than 12 years of age.

Drug interactions:
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially:
- If you are receiving tissue type plasminogen activator (tPA) as acute treatment for blood clots, you should not be treated with Ruconest at the same time.

Pregnancy, breast-feeding and fertility
There is no experience with the medicine in pregnant and breast-feeding women.
It is not recommended to use the medicine 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.

Important information about some of the ingredients of the medicine:
Ruconest contains sodium, about 19.5 mg per vial.
This should be taken into consideration by patients on a controlled sodium diet.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.
Check with your doctor or pharmacist if you are not sure about the dosage and the treatment regimen of the medicine.
The dosage and treatment regimen will be determined by the doctor only.
Treatment with Ruconest will be initiated by a doctor who is specialised in the diagnosis and treatment of hereditary angioedema.
The recommended dose is: up to 2 vials, will be worked out based on your weight.
Most of the time a single dose is sufficient, but your doctor may decide that an additional dose should be administered.
No more than 2 doses should be given within 24 hours.
The instructions for use are clearly described in the information intended for healthcare professionals only, given at the end of this leaflet.
Do not exceed the recommended dose.
Method of administration: intravenous injection over a period of approximately 5 minutes by your doctor or by a nurse.
Before administration, Ruconest needs to be dissolved in water for injections, by a healthcare professional.
If you took an overdose or if a child accidentally swallowed the medicine, immediately proceed to a doctor or to a hospital emergency room and bring the package of this medicine with you.
Adhere to the treatment regimen recommended by the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
If you have further questions regarding the use of the medicine, consult a doctor or pharmacist.

4. SIDE-EFFECTS

As with any medicine, the use of Ruconest may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of 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.

Common side effects - effects that appear in 1-10 users out of 100:
- Nausea

Uncommon side effects - effects that appear in 1-10 users out of 1,000:
- 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

If one of the side-effects appear or worsen, or if you suffer from side-effects that were not mentioned in the leaflet, consult your doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health through link "reporting side effects due to drug treatment" located in the home page of the Ministry of Health website (www.health.gov.il) which refers to online form, or by entering the following link: https://sideeffects.health.gov.il
Additionally, you may also report to Kamada LTD by email: pharmacovigilance@kamada.com

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
Do not use after the expiry date (exp. date) that appears on the carton and vial label. The expiry date refers to the last day of that month.

Storage condition:
Do not store at temperature above 25°C.
Store in the original package in order to protect from light.
Before administration, the product should be dissolved in water for injections by a healthcare professional.
This medicine should be used immediately after reconstitution.
Do not use this medicine if you notice particles in the solution or if the solution is discolored.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains: sucrose, sodium citrate dihydrate and citric acid monohydrate.

What does the medicine looks like and the contents of the pack
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.

License holder: Kamada Ltd., Beit Kama.

Manufacturer: Pharming Technologies B.V, Leiden, The Netherlands

Revised in June 2021 according to MOHs guidelines

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 151-22-33442-00

המידע שלהלן מיועד לאנשי צוות רפואי בלבד:
المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط:

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 (2 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, at the discretion of the physician.

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:

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

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.

Shelf life of the reconstituted solution

Reconstituted drug product is stable for 48 hours when stored between 5°C and 25°C. From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

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