RUCONEST® 2100 U powder and solvent for solution for injection

PATIENT EDUCATIONAL MATERIAL / CHECKLIST

General information

- Limited data exists on the use of RUCONEST® in home- or self-administration.
- Your doctor may decide that RUCONEST® can be administered at home e.g. by yourself or a family member.
- Use this educational material / checklist in conjunction with the package leaflet and ask your doctor if you have any questions.
- Necessary skills have to be acquired by non-healthcare professionals before using RUCONEST®, to ensure safe and effective administration at home.

Patient details

(Please fill in)

Your name: .....

Your weight (kg):.....

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Before using RUCONEST® at home
You must be informed about the following:

Have you been informed?
(Please tick if done.)

Indication:
Treatment of acute attacks of hereditary angioedema (HAE) in adults, adolescents and children (aged 2 years and above), due to C1 esterase inhibitor deficiency.
Please note: RUCONEST® is **only** used **to treat acute attacks** of this disease. ☐

Do not use RUCONEST® if you are allergic to rabbits or ingredients of RUCONEST®. ☐

Warnings and precautions:
- Risk of allergic reactions due to traces of rabbit protein in RUCONEST®.
  For signs and symptoms of allergic reactions: see the section on side effects in the package leaflet.
- Do not drive or use machines if you have dizziness or headache after RUCONEST® use. ☐

Using other medicines:
RUCONEST® should not be administered if you use tissue plasminogen activator at the same time.
This is a medicine to dissolve blood clots. ☐

Pregnancy and breast-feeding:
RUCONEST® use is not recommended. ☐

Dosage for administration into a vein for the bodyweight stated above:
- **Your required number** of powder vials ..... and solvent vials .....(Please fill in)
  (One of each if bodyweight is 42 kg or less and two of each if bodyweight is over 42 kg)
- **Your required volume** of prepared solution in total: ..... ml
  (= bodyweight in kg divided by three; maximum 28 ml) ☐
- **Volume per syringe** of prepared solution
  first syringe: ..... ml and second syringe: ..... ml

An additional dose (same dosage as above) can be administered, if your symptoms do not improve after:
- 120 minutes for adults and adolescents. ☐
- 60 minutes for children.

Possible side effects:
See section 4 of the package leaflet.
- Signs of allergic reactions, such as skin rash, breathing difficulties, face or tongue swelling. ☐
- Seek immediate medical advice if side effects – in particular signs of allergic reaction - occur.

Storage:
Not above 25 °C, away from children, powder vial in vial carton to protect from light.
Immediately use prepared RUCONEST® solution. ☐

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Have you been informed?
(Please tick if done.)

Disposal of used equipment:
Ask your doctor about proper disposal of all used materials, including partially used vials and infusion set, according to regulations in your country. ☐

Documentation of each treatment: e.g. date, time, batch number. ☐

Training to prepare and administer RUCONEST® solution.
- Allow the doctor to instruct you, using the instructions for use in section 3 of the package leaflet - starting with "Before you begin" and proceeding step by step up to step 14 - how to use RUCONEST® at home.
- Carefully **perform all steps as described in text and illustrations** in the instructions for use.
- **Never** use RUCONEST® by yourself **without** previous **training** from a healthcare professional. ☐

Please ask the doctor in case you have any questions relating to the instructions of use and write down the answers:
- Before you use: .....
  .....
- Preparation of solution: ..... ☐
  .....
  .....
- Intravenous administration: .....
  .....
  .....

Record any additional information ☐

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Have you been informed?
(Please tick if done.)

Evaluate: Are you able to prepare and administer RUCONEST® solution?

Do not self-use RUCONEST® if the answer to any of these questions is "no" and inform your doctor.

- Are you willing to self-prepare and self-administer RUCONEST® in the vein? ☐ yes ☐ no
- Are you physically capable of self-preparing and self-administering RUCONEST®? ☐ yes ☐ no
- Have you understood each step in the instructions for use provided in the package leaflet? ☐ yes ☐ no

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Seek immediate medical advice from a doctor or if needed, seek emergency treatment if:

- You are not successful in puncturing the vein or otherwise unable to administer the dose.
- You have a rapidly progressing, serious attack, e.g. swelling of the throat.
- You are unsure of how to carry out all steps properly.
- You have used too much RUCONEST®.
- You are experiencing that your symptoms do not start to disappear within 60 minutes (children 2-12 years) or within 120 minutes (adolescents and adults) after a second dose of RUCONEST®.
- You have signs of an allergic reaction during or after the RUCONEST® administration such as hives, rash, itching, dizziness, wheezing, difficulty breathing or your tongue swells.

Reporting of side effects

If you get any side effects talk, to your doctor.

You can also report side effects directly to the MHRA through the Yellow Card scheme.

You can report via:

- the Yellow Card website **www.mhra.gov.uk/yellowcard**
- the free Yellow Card app available from the **Apple App Store** or **Google Play Store**
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

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