RUCONEST® 2100 U powder and solvent for solution for injection

HEALTHCARE PROFESSIONAL EDUCATIONAL MATERIAL / CHECKLIST

The following is designed to support you in appropriate instruction and training of patients and/or their caregivers for preparation and administration of RUCONEST®. Please use this educational material / checklist in conjunction with the provided summary of product characteristics and package leaflet.

General information

Limited data exists on the use of RUCONEST® in home- or self-administration. The prescribing physician is responsible for providing appropriate training to the person who administers the product in the home setting. The physician must verify that all the necessary skills have been acquired by this person, such that RUCONEST® can be safely and effectively administered. The preparation and administration skills of this person must be reviewed regularly, to ensure that optimal practice is maintained.

Patient details

(Please fill in)

Patient identifier: .....

Patient age: .....

Patient weight (kg): .....

Type of patient/caregiver training:

☐ date of first training: .....

☐ date of refresher training: .....

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Evaluate the following and inform the patient / caregiver about this before releasing to use RUCONEST® at home

Evaluated and informed
(Please tick if done.)

Indication:
Treatment of acute angioedema attacks in adults, adolescents and children (aged 2 years and above) with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.
Ensure that the user understands RUCONEST® is used to treat acute attacks only. ☐

Contraindication:
Known or suspected allergy to rabbits or ingredients of RUCONEST®. ☐

Warnings and precautions:
- Risk of allergic reactions due to contained traces of rabbit protein.
  Patients must be aware that allergic reactions could develop throughout and after administration, and should be informed of early signs and symptoms of hypersensitivity reactions.
- No driving or using machines if dizziness or headache occur after RUCONEST® use. ☐

Interactions:
RUCONEST® should not be administered simultaneously with tPA. ☐

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

Dosage for the bodyweight stated above:
- **Number** of required powder vials ..... and solvent vials .....
  (one of each if bodyweight is 42 kg or less and two of each if bodyweight is over 42 kg)
- **Millilitres** of prepared solution: .....(bodyweight in kg divided by three; maximum 28 ml)
- **Volume** per syringe of prepared solution - first syringe: ..... ml and second syringe: ..... ml ☐

Additional dose:
In case of an insufficient clinical response, an additional dose (same dosage as above) can be administered if the patient has not responded adequately after:
- 120 minutes for adults and adolescents
- 60 minutes for children

No more than 2 doses should be given within 24 hours. ☐

Possible side effects:
Explain possible side effects (e.g. signs of allergic reactions) and actions to be taken if they 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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Evaluated and informed
(Please tick if done.)

Disposal of used equipment:
Inform 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. ☐

Patient training for preparation and administration of RUCONEST® solution.
Please instruct the patient using the instructions for use in section 3 of the provided package leaflet – starting with "Before you begin" and proceeding step by step up to step 14.
Caution the patient / caregiver that **all steps** be performed **as described in text and illustrations**. ☐

Recheck that patient / caregiver fully understands **preparation of solution**, in particular:
- To hold the adapter with one hand when securing the syringe on a vial until it stops.
- That 14 ml solvent are required to prepare the solution from one powder vial.
- How to withdraw liquid from a vial and minimise bubbles in the syringe.
- Not to shake when dissolving the powder to **minimise foaming**.
  Whilst foaming does not impact the quality and safety of the product, prevent that foam is transferred in the syringe.
- That a prepared solution must be clear and colourless. ☐

Recheck that patient/caregiver fully understands **administration of solution**, in particular:
- The required volume of prepared solution per syringe – never exceed 14 ml.
- Use of the tourniquet.
- Use of infusion set and ensuring that needle is in the vein and properly fixed.
- Gentle injection of the solution into a vein (14 ml over about 5 minutes).
- Changing the syringe on the infusion set if a second is required.
- Disposal of all used materials, including partially used vials, according to regulations in your country. ☐

Please ask the patient or caregiver if he or she has any questions relating to instructions of use; document and answer these:
- Before you use: .....
  .....
  .....
- Preparation of solution: .....
  .....
  .....
- Intravenous administration: .....
  .....
  ..... ☐

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Evaluated and informed
(Please tick if done.)

Record any additional information

Assess whether the patient / caregiver is able to prepare and administer RUCONEST® solution

Consider for evaluation the patient training and recheck of understanding. Do not allow self-administration if you answer one of the following five questions with "no".

- Is the patient / caregiver willing to use RUCONEST® in the home-care setting? ☐ yes ☐ no
- Is the patient / caregiver cognitively and physically (especially dexterity) able to use RUCONEST® in the home-care setting? ☐ yes ☐ no
- Does the patient have sufficient venous access? ☐ yes ☐ no
- Does the patient / caregiver understand each step in the instructions for use? ☐ yes ☐ no
- Is the patient / caregiver able to self-prepare and self-administer RUCONEST®? ☐ yes ☐ no

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Instruct the patient / caregiver in when to seek emergency treatment / advice

- If the patient or caregiver is unsuccessful in puncturing the vein or otherwise unable to administer the dose.
- If the patient experiences a rapidly progressing, serious attack - for instance swelling of the throat.
- If the patient is unsure whether all steps have been carried out properly.
- If the symptoms do not start to disappear within 60 minutes (children 2-12 years) or within 120 minutes (adolescents and adults) after the second dose of RUCONEST®.
- If the patient experiences signs of an allergic reaction during or after RUCONEST® administration, such as early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension, and anaphylaxis.

Healthcare professionals are encouraged to enrol patients in the post-marketing registry. For more information, please send an e-mail to **medinfo.ie@pharming.com**.

Please report any suspected adverse reactions via:

National reporting system:
HPRA Pharmacovigilance
Website: **www.hpra.ie**

Pharming:
safety.ie@pharming.com

Place and date ..... Signature of healthcare professional .....

Pharming

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