Rapilysin (Reteplase) 10ml Powder for Solution for Injection

Warnings and precautions

Children
There have been no effectiveness of Rapilysin in children have not been established. Treatment of children with Rapilysin is not recommended.

Other medicines and Rapilysin
Tell your doctor if you are taking, have recently taken or you may take any other medicines or herbal preparations.

Breast-feeding

If you plan any surgery, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Uncommon side effects (may affect up to 1 in 100 people)

References

Dosage of Rapilysin

1. Remove the protective flip-cap from the Rapilysin 10U and clean the rubber closure with an alcohol wipe.

2. Open the package containing the reconstitution solution, remove both protective caps from the reconstitution solution.

3. Insert the spike through the rubber closure into the vial of Rapilysin 10U.

4. Take the 10 ml syringe out of the package. Remove the tip cap from the syringe. Connect the syringe to the reconstitution solution and then flush the 10 ml of air into the vial of Rapilysin 10U.

5. With the reconstitution spike and spike still attached to the needle, you may also inject the reconstituted Rapilysin directly into the vein.

6. The recommended preparation results in a clear, colorless solution. However, if the solution is not clear and colorless it should be discarded.

7. Withdraw 10ml of Rapilysin 10U solution back into the syringe. A small volume of air should be left in the syringe to allow for the spike to draw back into the vial easily.

8. Discard the reconstitution solution. The dose is now ready for intravenous administration.

9. No other medicines should be injected through the line reserved for Rapilysin either at the same time, or prior to, or following Rapilysin injection. This applies to all medicines including heparin and anticoagulants, which are given by intravenous route.

10. Patients whose condition can change rapidly should be continually observed and examined.
5. How to store Rapilysin

- 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 container and on the label of the vial/infusion bag.
- Do not store above 25°C.
- Keep the seal in the vial/carton in order to protect from light.
- After reconstitution (“when dissolved”), the solution must be used immediately.

6. Contents of the pack and other information

- What Rapilysin contains
  - The active substance is reteplase 10U/10ml after reconstitution.
  - The other ingredients are:
    - Excipients:
      - Tranexamic acid
      - Di-potassium hydrogen phosphate
      - Sodium succinate acid
      - PEG 400
      - Polypropylene 80
    - Vial:
      - 1 vial for injection (sterile vial).
- What Rapilysin looks like and contents of the pack
  - Rapilysin is presented as a powder and a solvent for injection.
  - Vial: Reconstituted: 0.56 g powder in a vial with a reconstitution spike and a needle-pack of 2.

For any information about this medicine, please contact the local representation of the Marketing Authorisation Holder:

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Detailed information on this medicine is available on the European Medicines Agency website: [http://www.ema.europa.eu](http://www.ema.europa.eu)