RUCONEST Dose for

19 (9%)

28 mL

ORF

13 (28%)

8.0

MLV

2.2

0.8

0

healthcare provider or pharmacist for information about RUCONEST that was written

the leaflet, please inform your healthcare provider or pharmacist. You can also report

• headache

• faintness

• turning blue (look at lips and gums)

RUCONEST was a severe allergic reaction in a subject who was allergic to rabbits.

• Fever

• cold symptoms

• runny nose

• sore throat

It is possible that some of the symptoms listed above may be misleading.

Like all medicines, RUCONEST can cause side effects, although not everybody gets

them.

RUCONEST will be slowly injected into your vein (intravenous injection). Before

administering is based on body weight shown in the chart below.

PREPARATION OF MEDICATION AND MATERIALS

Step 1: Inspect RUCONEST vial(s) visually.

Remove the syringe and transfer the diluent to the RUCONEST vial. Add the diluent slowly to avoid

syringe clockwise.

When using a syringe and vial adapter, use a new vial adapter for each vial of RUCONEST and diluent.

Use the reconstituted product immediately, or within 8 hours stored at 2°C - 8°C (36°F - 46°F). Discard

not use if the solution is cloudy, colored, or contains particulates.

Step 5: Stand by the syringe

While holding the plunger of the syringe, insert the needle to the hub of the syringe. Do not plunge in

and press down until it

snaps into place.

Now, place a 2nd adapter over a

RUCONEST vial and press down until it

snaps into place.

Leaving the adapters in their packages.

Three randomized, placebo-controlled clinical trials (RCTs) were conducted in which 137 patients

received treatment with RUCONEST for a combined total of 650 acute angioedema attacks. Among these

patients, 105 (77%) had a history of angioedema attacks, of whom 89 (85%) were males. The mean age of

patients was 40.8 years (range of 16 to 71 years). The mean body weight of patients was 72 kg (range of

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Table 4. Viral reduction capacity of the rhC1INH manufacturing process

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Step 3: Mix hands.

With your hands and do your hands

Step 2: Place the adapter over the diluent vial

Without any vial adapter, attach syringe to diluent vial and inject 14 mL to the RUCONEST vial. If 28 mL

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*Note: All patients who received one dose of RUCONEST are included in the calculations.*

The safety and efficacy of RUCONEST in the treatment of acute attacks in patients with hereditary angioedema was established in Study 1, a double-blind, randomized, placebo-controlled trial (RCT) which included an open-label extension (OLE) of each of the three randomized studies.

The open-label extensions (OLE) of each of the three randomized studies included patients who had received RUCONEST 50 U/kg or 100 U/kg in the randomized phase, and who had a relapse of their symptoms within 24 hours of their previous dose. In Study 1, the OLE phase of the trial was conducted in 170 patients who had a relapse of their symptoms within 24 hours. The median time to beginning of relief in Study 1 was 120 minutes (95% CI: 100-140 minutes) in the treatment group compared with 240 minutes (95% CI: 200-280 minutes) in the placebo group. The hazard ratio for women receiving RUCONEST versus placebo was 1.22 (95% CI: 0.92-1.61) and for men receiving RUCONEST versus placebo was 1.36 (95% CI: 1.05-1.77). One possible explanation for the gender effect is that the median time to beginning of relief of symptoms in men was 1.4 times longer than in women. The relationship to elevated TPA antigen in patients with high PAI-1 activity levels. Circulation. 1997 Aug 15;96(3):730-5.

Table 7. Time to Beginning of Relief of Symptoms based on questionnaires based on 10.8.

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**ATTENTION!**

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**To be filled in by client**

Approved:

☐ YES

☐ NO

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**Date:**

**Name and signature:**

Dobber Healthcare Leaflets BV

Westerfer 13

Postbus 8, 1910 AA Uitgeest

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Fax +31 (0)25 131 3945

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