

RescueFlow[®]

Solution for Infusion

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The name of the medicinal product that has been given to you is RescueFlow Solution for Infusion.

RescueFlow is a solution which is clear and colourless and contains the following:

- The active substances are dextran 70 for injection 6% w/v, and sodium chloride 7.5% w/v.
- The other ingredients are water for injections and for pH adjustment hydrochloric acid/sodium hydroxide.

The marketing authorisation holder and company responsible for information about RescueFlow is:

BioPhausia AB
Blasieholmsgatan 2
SE-111 48 Stockholm, Sweden

RescueFlow is manufactured by:

Fresenius Kabi Norge AS
Svinesundsveien 80
NO-1753 Halden, Norway

1. WHAT IS RESCUEFLOW AND WHAT IS IT USED FOR

RescueFlow is a solution for infusion. It is a plasma substitute which quickly increases the circulating volume in the blood system and helps raise blood pressure.

RescueFlow is used in acute situations as initial treatment of blood loss and low blood pressure caused by trauma.

2. BEFORE YOU USE RESCUEFLOW

RescueFlow should not be given

- if you are known to be hypersensitive (allergic) to dextran or to any of the other ingredients of RescueFlow
- if you are pregnant around the time of delivery

Special care with RescueFlow should be taken

- if you are already using medicines known to affect blood clotting
- if you have a poor heart condition
- in certain severe cases if you have diabetes mellitus
- if you suffer from chronic renal failure

It is, however, obvious that in the acute situation when RescueFlow is used, this information may often not be known to the doctor. If these conditions are suspected, the potentially higher risks should be observed by the doctor and weighed against the expected benefit for the patient.

When possible please inform your doctor if you are taking or recently have taken any other medicines, even those not prescribed.

3. HOW TO USE RESCUEFLOW

One bag of RescueFlow, containing 250 ml, is given intravenously in two to five minutes as the initial treatment in the acute emergency situation. It is only given as a single dose, and is usually followed by infusion of other fluids based on the needs of the patient.

4. POSSIBLE SIDE EFFECTS

Like all medicines, RescueFlow can have side effects. Local pain close to the site of infusion can occur which can be attenuated by gentle massage close to the infusion site. No other side effects have been seen in the clinical trials.

Hypersensitivity reactions may rarely occur during treatment with dextran but no such reactions have been observed in the clinical trials where RescueFlow has been used in the emergency trauma situations.

In diabetics with hyperglycaemia (high blood sugar levels), hypertonic solutions such as RescueFlow should be used with caution.

RescueFlow should be used with caution in patients with any elements of heart failure.

Care will be needed in patients who are already on any drugs known to affect clotting, since large volumes of fluid could result in an increased risk of bleeding.

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

5. STORING OF RESCUEFLOW

There are no special storage instructions. This medicinal product should not be used after the expiry date stated on the label.

Further information

Further information about RescueFlow can be obtained from your doctor or pharmacist or from BioPhausia AB, Blasieholmsgatan 2, SE-111 48 Stockholm, Sweden

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This leaflet was last revised on 2008-01-24