Gelaspan solution for infusion

1. NAME OF THE MEDICINAL PRODUCT
Gelaspan solution for infusion

B. Braun Melsungen AG · 34209 Melsungen, Germany
SUMMARY OF PRODUCT CHARACTERISTICS

1. WHAT GELASPAR IS AND WHAT IT IS USED FOR
Gelaspar is used to replace blood and body fluid, which have been lost as a result of disease or injury.

2. HOW TO USE GELASPAR

Infusion rate:
- Gelaspar is given intravenously, i.e. by a drip.
- Infusion rate: 500 ml to 2 liters of infusion fluid per hour. The infusion rate must be adjusted according to the patient's clinical status. For children, the maximum infusion rate should not exceed 1.2 ml/kg/h.

3. POSSIBLE SIDE EFFECTS

Very rare:
- Hypokalaemia
- Hyperkalaemia

4. POSOLOGY AND METHOD OF ADMINISTRATION

Maximum dose:
- As with all blood substitutes, the maximum dose is limited to a maximum of 20 ml/kg body weight.
- The doctor will only administer this medicine to your child when he/she thinks it is essential for your child's recovery.

5. SPECIAL INSTRUCTIONS FOR ADMINISTRATION

- Gelaspar must not be infused through the same infusion line together with blood or blood components.
- If an overdose occurred your doctor will give you any necessary treatment.

6. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- Gelaspar should be administered with caution to patients with a history of allergic reactions.
- Extra precautions are necessary in patients with existing disorders of haemostasis.
- CHECKS OF SERUM ELECTROLYTE CONCENTRATIONS AND WATER BALANCE ARE NECESSARY, IN PARTICULAR IN PATIENTS WITH HYPERNATRAEMIA, HYPERKALAEIA OR IMPAIRMENT OF RENAL FUNCTION.

7. INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

- Gelaspar must not be used in patients who are taking medicines that make you retain sodium or potassium (e.g. spironolactone, triamterene).
- If you have problems with blood clotting, Gelaspar must not be administered.

8. INFORMATION FOR THE USERS

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you have any further questions, ask your doctor or pharmacist.

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Reporting of suspected adverse reactions

No special features

Immediately and the usual acute treatment given.

In the event of an anaphylactoid reaction, the infusion must be discontinued imme-

sionals only:

Calcium 1 mmol/l

Sodium acetate trihydrate 3.27 g

1000 ml of the solution contain:

What Gelaspan contains

Previously opened or partly used Gelaspan should be thrown away. Partial-

 leaking of the container.

Do not store above 25 °C. Do not freeze.

the outer carton. The expiry date refers to the last day of that month.

Keep out of the reach and sight of children.

ty@hpra.ie

Website: www.mhra.gov.uk/yellowcard

Yellow Card Scheme

provide more information on the safety of this medicine.

any possible side effects not listed in this leaflet. You can also report side

very rare:

fever, chills

Very rare:

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Unfortunately, there is no test which can show in advance who is likely to

allergic conditions such as asthma.

of solution, Gelaspan is a plasma substitute, not a plasma expander. The solution

the extravascular space.

blood, plasma and interstitial fluid. Thus the mean arterial pressure, the left-ven-

tral regarding clotting mechanisms.

Gelaspan does not interfere with the determination of blood groups and it is neu-

oud charges of gelatin (Gelatin 26,500 Dalton) and sodium acetate.

ATC code: B05A A06, gelatine agents.

Blood substitutes and plasma protein fractions

5.1 Pharmacodynamic properties

 consecutive impairment of heart and lung function (pulmonary oedema). Symptoms of

involvement of hypotension and circulatory overload are e.g. headache, dyspnoea, and jugular vein congestion.

Prevention of circulatory overload and hypotension is so adaptable that even under the condition of renal insufficiency no accu-

mulation of Gelaspan is observed.

After infusion, Gelaspan is rapidly distributed in the intravascular compartment.

organs and muscles.

shifts into the intracellular space as caused by hypotonic solutions. Gelaspan con-

It is designed for use in patients with a need for volume expansion, who are unable to respond adequately or whose response is unsatisfactory to fluid therapy with isotonic saline or crystalloids.

In hypovolemic or hypotensive patients, Gelaspan may be given in severe cases as a volume expander, possibly combined with other therapeutic interventions. Gelaspan is a plasma substitute. In severe forms of bleeding, Gelaspan may be used to restore circulatory volume (in combination with other haemodynamic measures).

In patients with impaired renal function and/or reduced GFR (GFR < 0.5 ml/min). Gelaspan minimizes the risks of dilutional acidosis and rebound

acidosis and rebound alkalosis, particularly in patients with ascites or with a reduced glomerular filtration rate (GFR < 0.5 ml/min).

Increased intravascular volume, dilutional alkalosis.

In severe forms of bleeding, Gelaspan may be used to restore circulatory volume (in combination with other haemodynamic measures). Gelaspan is not indicated as a therapeutic alternative in severe forms of bleeding. The volume of infused plasma is limited by the volume and dilution effects of Gelaspan.

Non-clinical data for the individual components of Gelaspan reveal no special haz-

diseases. Gelaspan contains acetate and is lactate free. It therefore can also be indi-

cated in hypovolaemic patients with liver disease.

There is no or limited non-clinical data available for reproductive toxicity.

No special pharmacokinetic properties of Gelaspan have been identified. Gelaspan is rapidly distributed to the intravascular compart-

ment where most of it is immediately metabolised (60% of the dose). The remaining 40% is excreted in faeces and not more than about 1 % is metabolised. The smaller mole-

elsewhere in the organism.

A decrease in haematocrit which is not augmented by volume expansion with Gelaspan. This decrease in haematocrit is not accompanied by a decrease in mean arterial pressure.

a fall in haematocrit and a consequent afterload reduction. The haematocrit is reduced less than that which is possible with mannitol as a diuretic, and the increase in blood volume is higher than with mannitol.

In a number of cases, a 100 ml bolus of Gelaspan may suffi-

cient time to define whether or not volume expansion will be successful.

The volume of fluid administered without resuscitation must never be sufficient to lead to overhydration. This statement does not apply to patients with ascites or other plasma leaks. Overhydration is a potentially serious complication of volume expansion.

The occurrence of anaphylactoid reactions is uncommon in Gelaspan. Anaphylactoid reactions are allergic manifestations of an allergic hypersensitivity reaction. Sometimes they can be so severe that they require immediate medical treatment.

Although anaphylactoid reactions are very rare, they may occur in patients with a history of allergies or who have had previous reactions to products containing gelatine. Where feasible, skin tests should be performed. In case of anaphylactoid reactions, the infusion must be discontinued immediately and the usual acute treatment given.

In the event of an anaphylactoid reaction, the infusion must be discontinued imme-

Diagnosis, using product labelling, labelling and advertising, crisis management.