PACKAGE LEAFLET: INFORMATION FOR THE USER
Gelaspan solution for infusion

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Gelaspan is and what it is used for

Gelaspan is a so-called plasma volume substitute. This means that it replaces fluid lost from your blood vessels.

Gelaspan is used to:
- Replace blood and body fluid, which have been lost following for example, an operation, an accident or a burn. It may be combined with blood transfusions, if necessary.
- Prevention of low blood pressure (hypotension) which may occur when you are receiving spinal or epidural anaesthesia or due to imminent severe blood loss in a surgical setting.
- Fill up the circulating blood volume during the use of for example heart-lung machine in combination with other fluids for infusion

2. What you need to know before you use Gelaspan

Do not use Gelaspan
- if you are allergic to gelatin or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to an allergen called “galactose-α-1,3-galactose (alpha-Gal)” or to red meat (mammal meat) and offal
- if your circulating blood volume is too large
- if you have too much water in your body
- if you have certain types of heart failure (acute congestive heart failure)
- if you have an abnormally high blood potassium level.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before using Gelaspan

Please inform your doctor

- if you suffer from allergic disease such as asthma. Then you may be at a greater risk of experiencing an allergic reaction
- in these cases, Gelaspan should not be given to you due to possible cross-reactions:
  - if you know you have an allergy to red meat (mammal meat) or offal
  - if you have been tested positive to antibodies (IgE) against the allergen alpha-Gal

Your doctor will take special care of your situation if you suffer from
- heart problems
- high blood pressure
- water on your lungs
- severe kidney problems

Giving large amounts of liquids through an intravenous drip may worsen your condition.

Your doctor will also exercise caution
- if you have a severe increase of sodium or chloride in your blood
- if you retain water and salt, which may be associated with tissue swelling
- if you have too much potassium in your blood or if you are taking or receiving medicines that make you retain potassium
- if your blood clotting is severely impaired
- if you are elderly

While receiving Gelaspan, your blood composition will be monitored. If necessary, your doctor may also give you other medications such as salts and fluids.

Children:
There is only little experience regarding the use of Gelaspan in children. The doctor will only administer this medicine to children when considered absolutely necessary.

Laboratory test results
Your doctor can take blood or urine samples before giving you Gelaspan. This is because some laboratory test results may be affected after you have received this medication and are therefore unreliable.

Other medicines and Gelaspan

Please tell your doctor or pharmacist if you are taking or using or have recently taken or used any other medicines, including medicines obtained without a prescription.

In particular your doctor should know if you are taking or receiving medicines that make you retain sodium (e.g. spironolactone, triamterene, amiloride; ACE-inhibitors like captopril or enalapril, corticosteroids like cortisone or non-steroidal anti-inflammatory agents like diclofenac). Concomitant administration with this medicine might lead to swelling of arms, hands, legs and feet (oedema). In addition, please inform your doctor if you are taking medications that make you lose potassium such as medicines that increase water loss.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy
If you are pregnant, please inform your doctor. Due to possible allergic reactions the use of this medicine should be avoided during pregnancy. However, your doctor may give you this medicine in emergency situations.

Breast-feeding
If you are breast-feeding, please inform your doctor. There is limited information about excretion of this medicine in breast-milk. Your doctor will decide whether to discontinue breast-feeding or to discontinue this medicine taking into account the benefit of breast-feeding for the child and the benefit of therapy for yourself.

Fertility
There are no data on the effect of this medicine on human or animal fertility. However, because of the nature of its constituents it is considered unlikely that it will affect fertility.

Driving and using machines

This medicinal product does not influence your ability to drive or use machines.

3. How to use Gelaspan

Your doctor only will give you Gelaspan, if they consider that other products called crystalloids are not sufficient alone.

Your doctor will adjust the dose of Gelaspan carefully in order to prevent fluid overload. This will be done especially if you have problems with your lungs or with your heart or circulation.

Dosage

Gelaspan is given intravenously, i.e. by a drip.

Adults
How much you are given and for how long will depend on how much blood or fluid you have lost and on your condition.

The doctor will carry out tests (on blood and blood pressure, for example) during treatment, and the dose of Gelaspan will be adjusted according to the patients needs. If necessary you may also receive blood or packed red blood cells.

Use in children
There is only little experience of the use of this medicine in children. Your doctor will only administer this medicine if they consider it essential for the child's recovery. In those cases, the clinical condition will be taken into account and therapy will be monitored especially carefully.

If you received more Gelaspan than you should

An overdose of Gelaspan may cause too high blood volume (hypervolaemia) and fluid overload that may affect your heart and lung function.
You may notice headaches and difficulties breathing.

If an overdose occurred your doctor will give you any necessary treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Gelaspan can cause side effects, although not everybody gets them.

All plasma substitutes carry a slight risk of allergic reactions that are mostly mild or moderate but can in very few cases also become severe. Such reactions are assumed to be more frequent in patients with known allergic conditions such as asthma. For that reason you will be under close observation by a health professional, especially at the beginning of the infusion.
The following side effects may be serious. If any of the following side effects occur, consult a doctor immediately:

Rare (may affect up to 1 in 1,000 people):
allergic (anaphylactic/anaphylactoid) reactions, including e.g. difficulty breathing, wheeze, nausea, vomiting, dizziness, sweating, chest or throat tightness, stomach ache, swelling of neck and face.
If an allergic reaction occurs your infusion will be stopped immediately and you will be given any necessary treatment (see also section 2 "What you need to know before you use Gelaspan", notably for allergies involving the allergen called galactose-α-1,3-galactose (alpha-Gal), red meat and offal).

Other side effects include:

Very common (may affect up to 1 in 10 people):
- a decrease of red blood cells and proteins in your blood

Common (may affect up to 1 in 100 people):
- your blood may not clot as well as before and you may notice more bleeding

Very rare (may affect up to 1 in 10 000 people):
- quickening of heartbeat
- low blood pressure
- fever, chills

Unknown (frequency cannot be estimated from the available data):
- feeling sick, being sick, stomach pain
- a decrease of oxygen in your blood which may make you feel dizzy

Additional side effects in children
There are no data relating a difference in side effects in children.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom (GB and NI):
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
Ireland:
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Gelaspan

Keep out of the reach and sight of children.

Do not use Gelaspan after the expiry date which is stated on the label and the outer carton. The expiry date refers to the last day of that month.

Do not store above 25 °C. Do not freeze.
Do not use Gelaspan if you notice:
- cloudiness or discolouration of the solution
- leaking of the container.

Previously opened or partly used Gelaspan should be thrown away. Partially used bottles or bags should not be reconnected.

6. Contents of the pack and other information

What Gelaspan contains

Active substances:

1000 ml of the solution contain:

Succinylated (modified fluid) gelatine	40.0 g
Sodium chloride	5.55 g
Sodium acetate trihydrate	3.27 g
Potassium chloride	0.30 g
Calcium chloride dihydrate	0.15 g
Magnesium chloride hexahydrate	0.20 g

Electrolyte concentrations

Sodium	151 mmol/l
Chloride	103 mmol/l
Potassium	4 mmol/l
Calcium	1 mmol/l
Magnesium	1 mmol/l
Acetate	24 mmol/l

The other ingredients are:
Water for injections, hydrochloric acid, diluted (for pH-adjustment) and sodium hydroxide (for pH adjustment).

What Gelaspan looks like and contents of the pack

Gelaspan is a solution for infusion administered through an intravenous drip (a drip into a vein).

It is a clear colourless or slightly yellowish sterile solution.

Gelaspan is supplied in:
- Bottles of low-density polyethylene “Ecoflac plus”, contents: 500 ml
  available in packs of 10 × 500 ml
- Plastic bags “Ecobag” (non-PVC), sealed with rubber stoppers, contents: 500 ml
  available in packs of 20 × 500 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany

Postal address
34209 Melsungen

Phone: +49-5661-71-0
Fax: +49-5661-4567

Manufacturer responsible for batch release UK

B. Braun Medical Limited
Brookdale Road
Thorncliffe Park Estate
Chapeltown
Sheffield
S35 2PW
United Kingdom

Manufacturer responsible for batch release ES & PT

B. Braun Medical S.A.
Carretera de Terrassa, 121
08191 Rubi (Barcelona)
Spain

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (GB and NI) under the following names:

Austria	Gelofusin Iso 40mg/ml Infusionslösung
Belgium	Isogelo oplossing voor infusie, solution pour perfusion, Infusionslösung
Bulgaria	Gelofusine Balance 4% solution for Infusion
Czech Republic	Gelaspan 4%
Germany	Gelafundin ISO 40mg/ml Infusionslösung
Denmark	Gelaspan
Estonia	Gelaspan infusioonilahus 4%
Greece	Gelaspan solution for Infusion 4%
Spain	Gelaspan 40mg/ml solución para perfusión
France	Gelaspan, solution pour perfusion
Hungary	Gelaspan 4% oldatos infúzió
Ireland	Gelaspan Solution for Infusion
Italy	Gelaspan
Lithuania	Gelaspan 4% infuzinis tirpalas
Luxembourg	Gelafundin ISO 40mg/ml Infusionslösung
Latvia	Gelaspan 4% Solution for Infusion
Malta	Gelaspan 4% Solution for Infusion
Norway	Gelaspan
Netherlands	Gelaspan, oplossing voor infusie
Portugal	Gelaspan
Poland	Gelaspan
Romania	Gelaspan 40 mg/ml solutie perfuzabila
Sweden	Gelaspan
Slovenia	Gelaspan 40 mg/ml raztopina za infundiranje
Slovakia	Gelaspan 4%
United Kingdom (GB and NI)	Gelaspan solution for infusion

This leaflet was last revised in April 2023.

The following information is intended for health-care professionals only:

Precautions for use
Gelaspan must not be infused through the same infusion line together with blood or blood products (packed cells, plasma and plasma fractions).

During compensation of severe blood losses by infusions of large amounts of Gelaspan, haematocrit and electrolytes must be monitored. The haematocrit should not decrease below 25 %. In elderly or critically ill patients it should not fall below 30%.

Likewise in those situations the dilution effect on coagulation factors should be observed, especially in patients with existing disorders of haemostasis.

Because the product does not substitute lost plasma protein, it is advisable to check the plasma protein concentrations.

In severe, acute situations, Gelaspan may be infused rapidly by pressure infusion, 500 ml can be administered in 5-10 minutes, until signs of hypovolaemia are relieved.

Before rapid infusion, Gelaspan may be warmed to not more than 37 °C.
In cases of pressure infusion which might be necessary in vital emergencies, all air must be removed from the container and the infusion set before the solution is administered. This is to avoid the risk of air embolism that might otherwise be associated with the infusion.

Influence on laboratory tests
Laboratory blood tests (blood group or irregular antibodies) are possible after Gelaspan infusions. Nevertheless it is recommended to draw blood samples before the infusion of Gelaspan in order to avoid hampered interpretation of results.

Gelaspan may have an influence on the following clinical-chemical tests, leading to falsely high values:
- erythrocyte sedimentation rate,
- specific gravity of urine,
- unspecific protein assays, e.g. the Biuret method.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.