

Patient Information Leaflet for Medicines for Human Use**SCHEDULING STATUS****S3****GELASPAN 4 % solution for infusion**

Succinylated gelatine (= modified fluid gelatine)

Balanced electrolyte solution

Read all of this leaflet carefully before you start taking GELASPAN 4 %

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- GELASPAN 4 % has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What GELASPAN 4 % is and what it is used for
2. What you need to know before you use GELASPAN 4 %
3. How to use GELASPAN 4 %
4. Possible side effects
5. How to store GELASPAN 4 %
6. Contents of the pack and other information

- 1. What GELASPAN 4 % is and what it is used for**

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GELASPAN 4 % is a plasma volume substitute. This means, it replaces fluid lost from the blood vessels. It is used to replace blood and bodily fluid, which have been lost following, for example, an operation, an accident or a burn. It may be combined with blood transfusions, if necessary.

GELASPAN 4 % may be used for:

- the treatment of low blood volume (hypovolaemia) and shock
- prevention and treatment of low blood pressure (hypotension) for example when you are receiving spinal or epidural anaesthesia or before you have surgery
- facilitating procedures involving blood being taken from a patient's circulation to have process applied to it before it is returned to the circulation (e.g., heart-lung machine).

2. What you need to know before you take GELASPAN 4 %**Do not use GELASPAN 4 %:**

- If you are allergic (hypersensitive) to gelatine or any of the other ingredients of GELASPAN 4 %
- 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 excess fluid in your body
- in children under 1 year of age
- If you are at markedly increased risk of bleeding because your blood clotting is severely impaired

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- if you have certain types of heart failure (acute congestive heart failure).

Warnings and precautions

Your doctor will take special care with GELASPAN 4 % if you suffer from:

- water in your lungs
- high blood pressure
- heart or your kidneys because giving large amounts of liquids through an intravenous drip may affect these organs.

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
- If you are suffering from allergic diseases such as asthma because you may be at a greater 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.

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In these cases, GELASPAN 4 % 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.

While receiving GELASPAN 4 %, 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 4 % in children. The doctor will only administer this medicine to children when considered necessary.

Laboratory test results: Your doctor can take blood or urine samples before giving you GELASPAN 4 %. This is because some laboratory test results may be affected after you have received this medication and are therefore unreliable.

Taking other medicines with GELASPAN 4 %:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Caution should be advised if you are taking or receiving medicines that cause sodium retention:

- Corticosteroids (cortisone-like medicines) are used to provide relief for inflamed areas of the body
- Non-steroidal anti-inflammatory drugs (NSAIDs) are commonly used to manage the pain and inflammation associated with arthritis and other musculoskeletal disorders
- Potassium sparing diuretics (they are used to increase the amount of fluid passed from the body in urine, whilst also preventing too much potassium being lost with it)

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- ACE inhibitors help relax your veins and arteries to lower your blood pressure
- Cyclosporine (belongs to a class of drugs known as immunosuppressant's)
- Tacrolimus or suxamethonium (used for muscular relaxation) can increase potassium levels
- Potassium containing solutions may lead to cardia arrhythmia (irregular and fast heart beat).

Pregnancy, breastfeeding, and fertility*Pregnancy*

There is no adequate data from the use of GELASPAN 4 % in pregnant woman. Due to the limited data the use of GELASPAN 4 % solutions during pregnancy should be restricted to emergency situations.

Breastfeeding

There is no data with regard to the excretion of GELASPAN 4 % into the mother's milk. However, it is unlikely because of its composition mass (molecular weight).

Fertility

There is no data on the effect of GELASPAN 4 %. However, because of the nature of its parts in the finished mixture it is considered unlikely.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

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It is not always possible to predict to what extent GELASPAN 4 % may interfere with the daily activities of a patient.

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GELASPAN 4 % affects them.

3. How to take GELASPAN 4 %

Always take GELASPAN 4 % exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with GELASPAN 4 % will last. If you have the impression that the effect of GELASPAN 4 % is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you how long your treatment with GELASPAN 4 % will last.

The dose of medicine given to you will depend on how much are you given and for how long will depend on how much blood or fluid you have lost on your condition.

GELASPAN 4 % is given intravenously, i.e by drip.

For children the doctor will determine the dose especially carefully. A child will receive this medicine only if the doctor considers it essential for his/ her recovery.

As this medicine will be given to you whilst you are in hospital it is unlikely that you will be given too little or too much, however tell you doctor or pharmacist if you have any concerns.

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The doctor will carry out tests (on your blood and blood pressure, for example) during your treatment and the dose of GELASPAN 4 % will be adjusted according to your needs.

If you take more GELASPAN 4 % than you should*Signs and Symptoms*

Since a healthcare provider will administer GELASPAN 4 %, he/ she will control the dosage. However, in the event of over dosage your doctor will manage over dosage.

An overdose of GELASPAN 4 % may give rise to circulatory overload and to alterations of your blood salt (electrolyte) levels.

If you forget to take GELASPAN 4 %

Since a health care provider will administer GELASPAN 4 %, it is unlikely that the dose will be missed.

4. Possible side effects**GELASPAN 4 % can have side effects.**

Not all side effects reported for GELASPAN 4 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GELASPAN 4 %, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking GELASPAN 4 % and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Severe acute hypersensitivity (allergic) reactions and anaphylactic shock
- Skin rash, itching and difficulty in breathing can be signs of acute hypersensitivity.

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These are all very serious side effects. If you have them, you may have had a serious reaction to GELASPAN 4 %. You may need urgent medical attention or hospitalisation.

- Allergic shock
- Fall in blood pressure
- Brochchospasm
- Cardiac or respiratory problems
- Anaemia
- Thrombosis (blood clots).

Such reactions can occur both in conscious and anaesthised patients.

These are all serious side effects. You may need urgent medical attention.

Less frequent side effects:

- Low blood pressure
- Fever, chills
- Nausea, vomiting
- Abdominal pain.

Not all side effects reported for GELASPAN 4 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GELASPAN 4 % please consult your health care provider for advice.

Patient Information Leaflet for Medicines for Human Use**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of GELASPAN 4 %.

5. How to store GELASPAN 4 %

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information**What GELASPAN 4 % contains***Active substance*

1000 mL of GELASPAN 4% solution for infusion contains:

Succinylated (modified fluid) gelatine 40,0 g

Sodium chloride 5,55 g

Sodium acetate trihydrate 3,27 g

Electrolyte concentrations

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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 4 % looks like and contents of the pack

- Ecoflac plus (Polyethylene plastic container), content 500 mL. Available in packs of 10 x 500 mL.
- Ecobags® with an injection port and a connection port for infusion. These ports are sealed by polypropylene caps with halogen-butyl rubber stoppers, contents of 500 mL. Available in packs of 20 x 500 mL.

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Holder of the certificate of registration

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