

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

Volulyte 6% solution for infusion

Hydroxyethyl starch (HES 130/0.4) in isotonic sodium chloride solution

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Volulyte is and what it is used for

Volulyte is a plasma volume substitute that is used to restore the blood volume when you have lost blood when other products called crystalloids are not considered sufficient alone.

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2. What you need to know before you use Volulyte

Do not use Volulyte if you:

- are allergic to any of the active substances or any of the other ingredients of this medicine
- suffer from serious generalised infection (sepsis)
- suffer from burn injury
- have kidney impairment or receive dialysis
- suffer from bleeding in the brain (intracranial or cerebral bleeding)
- are critically ill (e.g. you need to stay in an intensive care unit)
- have too much fluid in your body and you have been told that you have a condition known as hyperhydration
- have fluid in the lungs (pulmonary oedema)
- are dehydrated
- have been told that you have a severe increase of potassium, sodium or chloride in your blood
- have severely impaired liver function
- have severe heart failure
- have severe problems with your blood clotting
- have received an organ transplant

Warnings and Precautions

It is important to tell your doctor if you have:

- impairment of your liver function
- problems with your heart or circulation
- blood clotting (coagulation) disorders
- problems with your kidneys
- increased potassium, sodium, magnesium, chloride or alkaline levels in your blood (hyperkalaemia, hypernatraemia, hypermagnesaemia, hyperchloraemia)

Because of the *risk of allergic* (anaphylactic/anaphylactoid) reactions, you will be monitored closely to detect early signs of an allergic reaction when you receive this medicine.

Surgery and trauma:

Your doctor will consider carefully if this medicine is suitable for you.

Your doctor will adjust the dose of Volulyte 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.





The nursing staff will also take measures to observe your body's fluid balance, blood salt level, and kidney function. If necessary you may receive additional salts.

In addition it will be ensured that you receive enough fluids.

Volulyte is contraindicated if you have kidney impairment or kidney injury requiring dialysis.

If impaired kidney function occurs during therapy:

If the doctor detects first signs of kidney impairment he/she will stop giving you this medicine. In addition your doctor may need to monitor your kidney function for up to 90 days.

If you are given Volulyte repeatedly your doctor will monitor the ability of your blood to clot, bleeding time and other functions. In case of an impairment of the ability of your blood to clot, your doctor will stop giving you this medicine.

If you are undergoing open heart surgery and you are on a heart-lung machine to assist in pumping your blood during the surgery, the administration of this solution is not recommended.

Children

The safety of this product has not been assessed in children. Data are limited in children, therefore it is recommended not to use HES products in this population.

Other medicines and Volulyte

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. To date, Volulyte is not known to have any interactions with other medicines.

Volulyte with food and drink

Volulyte is not known to have any negative effect when given at the same time as food or drink.

Pregnancy and breast-feeding

For Volulyte no clinical data on exposed pregnancies are available. The safety of the product in pregnant and breast-feeding women has not been investigated. There are limited clinical study data available from the use of a single dose of HES 130/0.4 (6%) in 0.9% sodium





chloride in pregnant women undergoing caesarean section with spinal anesthesia. No negative influence of HES 130/0.4 (6%) in 0.9% sodium chloride on patient safety could be detected; a negative influence on the neonate could also not be detected.

Your doctor will only give Volulyte after having weighed the benefits versus the potential risk to the baby.

Driving and using machines

After receiving Volulyte, your ability to drive a car or operate machinery will not be affected.

3. How to use Volulyte

Volulyte will be given by, or under the direct supervision of, your physician, who will closely control the amount of Volulyte given to you.

Mode of administration

You will receive this medicine by infusion into a vein (intravenous drip). The speed of infusion, along with the amount of solution infused, will depend on your specific requirements, the disease for which the product is being used, and by reference to maximum daily dose.

Dosage

Your doctor will decide on the correct dose for you to receive.

Your doctor will use the lowest possible effective dose and will not infuse Volulyte for more than 24 hours.

The maximum daily dose is 30 ml/kg for Volulyte.

Use in children

There is only limited experience of the use of this medicine in children. Therefore it is not recommended to use this medicine in children.

If you have received more Volulyte than you should

Your doctor will ensure that you receive the right amount of Volulyte. However, different people need different doses, and if the dose does prove too much for you, your doctor may stop Volulyte immediately and, if necessary, administer a medicine that removes water from the body (diuretic).

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





4. Possible side effects

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

Common (may affect up to 1 in 10 people)

- Itching is a known side effect of hydroxyethyl starches when used over long periods of time and at high doses.
- Other effects are associated with the dilution of the blood, which occurs at high dosages, such as prolonged blood clotting time.
- The level of the enzyme serum amylase can rise during administration of hydroxyethyl starch and can interfere with the diagnosis of inflammation of the pancreas (pancreatitis). However, in this case the elevated serum amylase level must not be considered diagnostic of pancreatitis.

Rare (may affect up to 1 in 1,000 people)

- Medicinal products containing hydroxyethyl starch may lead to severe allergic reactions (reddening of the skin, swelling of the throat, and difficult breathing, mild influenza like symptoms, low or high heart rate, fluid in the lungs not caused by heart problems).
- After administration of hydroxyethyl starch disturbances of blood clotting can occur depending on the dose.

Frequency not known (cannot be estimated from the available data)

- Kidney injury
- Liver injury

Reporting of side effects

If you get any 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 directly:

For UK: via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

For IE: Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the HPRA at: IMB via freepost, to the following address:





HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie.

For MT: to the Medicines Authority at the following contact details
ADR Reporting
The Medicines Authority
Post-Licensing Directorate
203 Level 3, Rue D'Argens
GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Volulyte

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special storage conditions.
- Do not freeze.

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

Your doctor or nurse will ensure that the solution is clear, free from particles, the container undamaged and the overwrap is removed from the polyolefin (**freeflex**) bag before use.

The solution should be used immediately after opening, and any solution remaining after treatment should be discarded. For single use only.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.





6. Contents of the pack and other information

What Volulyte contains

1000 ml solution for infusion contain:

Active substances:

Poly(O-2-hydroxyethyl)starch (Ph. Eur.)	60.00 g
- Molar substitution: 0.38 – 0.45	
- Mean molecular weight (M_w):	130,000 Da
(manufactured from waxy maize starch)	
Sodium acetate trihydrate	4.63 g
Sodium chloride	6.02 g
Potassium chloride	0.30 g
Magnesium chloride hexahydrate	0.30 g

Electrolytes:

Na^+	137.0 mmol/l
K^+	4.0 mmol/l
Mg^{++}	1.5 mmol/l
Cl^-	110.0 mmol/l
CH_3COO^-	34.0 mmol/l

Theoretical osmolarity:	286.5 mosm/l
Titrateable acidity:	< 2.5 mmol NaOH/l
pH:	5.7 – 6.5

Other ingredients: Sodium hydroxide, hydrochloric acid, water for injections.

What Volulyte looks like and contents of the pack

Volulyte is a sterile, clear to slightly opalescent solution, colourless to slightly yellow. It is contained in:

- flexible bags made of polyolefin (**freeflex**)
- in a glass bottle
- in a polyethylene bottle (KabiPac).

All container types are available in 250 ml and 500 ml sizes.





Marketing Authorisation Holder and Manufacturer

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Manufacturer:
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Fresenius Kabi Polska Sp. z o.o.
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Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Volulyte 6% Infusionslösung

Belgium: Volulyte 6% oplossing voor infusie

Bulgaria: Volulyte 6% solution for infusion

Cyprus: Volulyte 6% Solution for Infusion

Czech Republic: Volulyte 6%

Denmark: Volulyte

Estonia: Volulyte 6% infusioonilahus

Finland: Volulyte 60 mg/ml infuusioneste, liuos

Germany: Volulyte 6% Infusionslösung

Greece: Volulyte 6% Solution for Infusion

Hungary: Volulyte 6% oldatos infúzió

Ireland: Volulyte 6% Solution for Infusion

Iceland: Volulyte 60 mg/ml innrennslið, lausn





Italy: Volulyte 6% Soluzione per infusione
Lithuania: Volulyte 6% infuzinis tirpalas
Latvia: Volulyte 6% šķidums infuzijam
Luxembourg: Volulyte 6% Infusionslösung
Malta: Volulyte 6% Solution for Infusion
Netherlands: Volulyte 6% oplossing voor infusie
Norway: Volulyte 60 mg/ml infusjonsvæske, oppløsning
Poland: Volulyte 6%
Portugal: Volulyte Solução para Perfusão
Romania: Volulyte 6%, solutie perfuzabila
Sweden: Volulyte 60 mg/ml infusionvätska, lösning
Slovakia: Volulyte 6%, infúzny roztok
Slovenia: Volulyte 60mg/ml raztopina za infundiranje
Spain: Volulyte 6% solución para perfusión
UK: Volulyte 6% Solution for Infusion

This leaflet was last revised in August 2017.





The following information is intended for healthcare professionals only:

Use of HES should be restricted to the initial phase of volume resuscitation with a maximum time interval of 24 h.

The maximum daily dose is 30 ml/kg for Volulyte.

The lowest possible effective dose should be applied. Treatment should be guided by continuous haemodynamic monitoring so that the infusion is stopped as soon as appropriate haemodynamic goals have been achieved. The maximum recommended daily dose must not be exceeded.

The first 10-20 ml should be infused slowly and under careful monitoring of the patient so that any anaphylactic/anaphylactoid reaction can be detected as early as possible.

The duration of treatment depends on:

- the extent of the low blood volume
- blood pressure
- the dilution of blood and its components (platelets, red blood cells etc.).

Use in children

Data are limited in children, therefore it is recommended not to use HES products in this population.

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

For single use only.

The product should be used immediately after first opening.

Any unused product or waste material should be disposed of in accordance with local requirements.

Use only clear, particle-free solutions and undamaged containers.

Remove the overwrap from the Polyolefin (**freeflex**) bag prior to use.



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