Electrolytes:	
Na^+	154 mmol/l
Cl^-	154 mmol/l
Theoretical osmolarity:	308 mosm/l
Titrable acidity:	< 1.0 mmol NaOH/l
pH:	4.0 – 5.5

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

What Voluven 10 % looks like and contents of the pack
Voluven 10 % is a sterile, clear to slightly opalescent solution, colourless to slightly yellow. It is contained in:
- flexible bags made either of polyolefin (**free***flex*) or
- in a PE container.

Polyolefin bag (**free***flex*) with overwrap:
1 x 500 ml, 10 x 500 ml, 20 x 500 ml

Polyethylene bottle (KabiPac, made from LDPE): 1 x 500 ml, 10 x 500 ml, 20 x 500 ml
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way, Manor Park,
Runcorn, Cheshire, WA7 1NT, UK

Manufacturer:
Fresenius Kabi Deutschland GmbH
61346 Bad Homburg v.d.H.
Germany

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

Germany:	Voluven 10 % Infusionslösung
Belgium:	Voluven, 10 % (100 mg/ml) oplossing voor infusie
Bulgaria:	Волувен 10 %
Cyprus:	Voluven 10 %, διάλυμα για έγχυση
Czech Republic:	Voluven 10 %
Denmark:	Voluven 100 mg/ml
Estonia:	Voluforte
Greece:	Voluven 10 %, διάλυμα για έγχυση
Finland:	Voluven 100 mg/ml
Hungary:	Voluven 10 % oldatos infúzió
Ireland:	Voluven 10 %
Italy:	Vonten
Lithuania:	Voluforte 10 % infuzinis tirpalas
Latvia:	Voluforte šķīdums infūzijām
Netherlands:	Voluven, 10 % (100 mg/ml) oplossing voor infusie
Poland:	Voluven 10 %
Portugal:	Voluven 10 % Fresenius
Sweden:	Voluven 100 mg/ml infusionsvätska, lösning
Slovenia:	Voluven 100 mg/ml raztopina za infundiranje
Slovak Republic:	Voluven 10 %
United Kingdom:	Voluven 10 %

This leaflet was last revised in 02/2016.

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 18 ml/kg for Voluven 10 %.

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 anaphylactoid/anaphylactic reaction can be detected as early as possible.

If an anaphylactoid/anaphylactic reaction occurs the infusion should be discontinued immediately and appropriate emergency medical treatment initiated.

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

For single use only.

To be used immediately after the bottle or bag is opened.

Any unused solution should be discarded.

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

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

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Voluven 10 % 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 or pharmacist.
– 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Voluven 10 % is and what it is used for
Voluven 10 % 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.

2. What you need to know before you use Voluven 10 %
Do not use Voluven 10 % 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 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

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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

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 Voluven 10 % 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.

Voluven 10 % 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 Voluven 10 % 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
Data are limited in children, therefore it is recommended not to use HES products in this population.

Other medicines and Voluven 10 %
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. To date, Voluven 10 % is not known to have any interactions with other medicines.

Voluven 10 % with food and drink
Voluven 10 % is not known to have any negative effect when given at the same time as food or drink.

Pregnancy and breast-feeding
There are no data from the use of the product in pregnant and breast-feeding women. Your doctor will only give Voluven 10% after having weighed the benefits versus the potential risk to the baby. Your doctor will advise you whether to interrupt breast-feeding or not.

Driving and using machines
After receiving Voluven 10 % your ability to drive a car or operate machinery will not be affected.

3. How to use Voluven 10 %
Voluven 10 % will be given by, or under the direct supervision of your physician, who will closely control the amount of Voluven 10 % 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 Voluven 10 % for more than 24 hours.

The maximum daily dose is 18 ml/kg for Voluven 10 %.

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 Voluven 10 % than you should
As with all volume substitutes, if you receive too much of Voluven 10 % your circulatory system can get overloaded, which can result e.g. in water retention in your lungs (lung oedema).

Your doctor will ensure that you receive the right amount of Voluven 10 %. However, different people need different doses, and if the dose does prove too much for you, your doctor may stop Voluven 10 % 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, Voluven 10 % can cause side effects, although not everybody gets them.

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people
not known:	frequency cannot be estimated from the available data

Blood and lymphatic system disorders:
Rare (may affect up to 1 in 1,000 people): After administration of hydroxyethyl starch, disturbances of blood clotting beyond dilution can occur depending on the dose.

Immune system disorders
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, mild influenza like symptoms, low or high heart rate, swelling of the throat and difficult breathing, fluid in the lungs not caused by heart problems).

Skin and subcutaneous tissue disorders
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.

Investigations
Common (may affect up to 1 in 10 people): 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.

Other effects are associated with the dilution of the blood, which occurs at high dosages, such as prolonged blood clotting time.

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 IMB via freepost, to the following address:

FREEPOST
IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2

Tel.: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie.

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

5. How to store Voluven 10 %
Keep this medicine out of the sight and reach of children.

Do not freeze.

Do not use Voluven 10 % after the expiry date (MM YYYY) 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 (**free***flex*) 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 Voluven 10 % contains

1000 ml solution for infusion contain:

Active substances:

Poly(O-2-hydroxyethyl)starch (Ph.Eur.)	100 g
– Molar substitution: 0.38 – 0.45	
– Mean molecular weight: 130,000 Da	
(manufactured from waxy maize starch)	
Sodium chloride	9 g

PACKAGE LEAFLET: INFORMATION FOR THE USER

Voluven 10 % solution for infusion

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

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- 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.
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- suffer from burn injury
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- suffer from bleeding in the brain (intracranial or cerebral bleeding)
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- 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 sodium or chloride in your blood
- have severely impaired liver function
- have severe heart failure
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- have received an organ transplant

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Dosage
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Use in children
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FREEPOST
IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie.

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

5. How to store Voluven 10 %

Keep this medicine out of the sight and reach of children.

Do not freeze.

Do not use Voluven 10 % after the expiry date (MM YYYY) 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 (**free***flex*) 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.

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1000 ml solution for infusion contain:

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Titratable acidity:	< 1.0 mmol NaOH/l
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WA7 1NT, UK

Manufacturer:
Fresenius Kabi Deutschland GmbH
61346 Bad Homburg v.d.H.
Germany

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Germany: Voluven 10 % Infusionslösung

Belgium: Voluven, 10 % (100 mg/ml) oplossing voor infusie

Bulgaria: Волувен 10 %

Cyprus: Voluven 10 %, διάλυμα για έγχυση

Czech Republic: Voluven 10 %

Denmark: Voluven 100 mg/ml

Estonia: Voluforte

Greece: Voluven 10 %, διάλυμα για έγχυση

Finland: Voluven 100 mg/ml

Hungary: Voluven 10 % oldatos infúzió

Ireland: Voluven 10 %

Italy: Vonten

Lithuania: Voluforte 10 % infuzinis tirpalas

Latvia: Voluforte šķīdums infūzijām

Netherlands: Voluven, 10 % (100 mg/ml) oplossing voor infusie

Poland: Voluven 10 %

Portugal: Voluven 10 % Fresenius

Sweden: Voluven 100 mg/ml infusionsvätska, lösning

Slovenia: Voluven 100 mg/ml raztopina za infundiranje

Slovak Republic: Voluven 10 %

United Kingdom: Voluven 10%

This leaflet was last revised in 02/2016.

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