APPROVED PATIENT INFORMATION LEAFLET

VOLUVEN®

Scheduling status

S3

Proprietary name and dosage form

VOLUVEN®, solution for infusion

Hydroxyethyl starch in an electrolyte solution

Read all of this leaflet carefully before you receive Voluven

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Voluven 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 VOLUVEN CONTAINS

The active ingredients are:

Poly(O-2-hydroxyethyl)starch	60,00 g
- Molar substitution 0,38 – 0,45	
Sodium chloride	9,00 g

Electrolytes:

Na^+	154 mmol/l
Cl^-	154 mmol/l
Theoretical osmolarity	308 mOsm/l

pH 4,0 – 5,5

The other ingredients are: Sodium hydroxide, hydrochloric acid and water for injections.

WHAT VOLUVEN IS USED FOR

Voluven is given in combination with crystalloids, for the treatment of adults and children with severe blood loss (hypovolaemia) during surgical operations and/or with trauma (injury or wound).

Voluven is not intended for newborn babies (babies younger than 1 month old).

BEFORE YOU ARE GIVEN VOLUVEN

You should not be administered Voluven if:

- you are allergic (hypersensitive) to starch (see POSSIBLE SIDE EFFECTS)
- you are critically ill with or without blood infections/blood poisoning (sepsis/septicaemia)
- you have severe burns
- your kidneys do not work well
- you have severe liver problems
- you have kidney failure and you produce little or no urine
- you have lost too much fluid (moderate to severe dehydration)
- you have too much fluid in your body (over-hydration) with or without fluid accumulation in the lungs (pulmonary oedema)
- you have congestive heart failure (a condition in which your heart cannot pump enough blood to other organs of your body)

- you already have blood clotting (coagulation) or bleeding disorders
- you suffer from bleeding within or around the brain (intracranial bleeding)
- you have very high levels of sodium or chloride in your blood (severe hypernatraemia, severe hyperchloraemia)
- you are receiving dialysis treatment (an artificial kidney treatment).

Take special care with Voluven

Tell your doctor or healthcare professional before being given Voluven

Your doctor may need to take special precautions if you have to undergo an organ transplant operation or a cardiac bypass operation. Your doctor will decide whether you can receive Voluven if you suffer from:

- problems with your circulation, heart or kidneys, as there is an increased risk of fluid overload with the use of Voluven
- you have increased levels of sodium or chloride in your blood (hypernatraemia, hyperchloraemia)
- if you are older than 65 years of age.

You (or your child) should not be treated for more than 24 hours with Voluven.

Receiving Voluven with food and drink

Voluven is not known to have any interactions when given at the same time as food or drink.

Pregnancy and breastfeeding

The safety of the use of Voluven in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving Voluven.

Driving and using machinery

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

Taking other medicines with Voluven

Always tell your doctor if you are taking any other medicine. (This includes complementary or traditional medicines).

The use of Voluven with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO RECEIVE VOLUVEN

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself Voluven.

Voluven will be given by, or under close supervision of your doctor. Your doctor will closely control the amount of Voluven given to you.

Mode of administration

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

Dosage

Your doctor will decide on the correct dose and the duration of treatment.

VOLUVEN should not be used in newborn babies (babies less than 1 month old).

If you have the impression that the effect of Voluven is too strong or too weak for you, tell your doctor or pharmacist.

If you have received more Voluven than you should

Since a healthcare professional will administer Voluven, he/she will control the dosage. However, in the event of overdosage you doctor will manage the overdosage.

POSSIBLE SIDE EFFECTS

Voluven can have side effects.

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

The following symptoms are very serious; you must contact your doctor immediately if any of these side effects occur:

Anaphylactic/anaphylactoid reactions may occur (severe allergic reaction with e.g. reddening of the skin, swelling of the throat, and difficulty in breathing, influenza like symptoms, low or high heart rate and/or fluid in the lungs not caused by heart problems).

These are all a very serious side effects. If you have them, you may have had a serious allergic reaction to Voluven. You may need urgent medical attention and further hospitalisation.

Tell your doctor if you notice any of the following:

- Increased serum amylase during administration of Voluven which may interfere with the diagnosis of inflammation of the pancreas (pancreatitis).
- Itching
- Administration of high doses may result in a corresponding dilution of blood components e.g. coagulation (clotting) factors and other plasma proteins, resulting in prolonged clotting time or bleeding.
- Disturbances of blood clotting beyond effects caused by dilution of your blood can occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist**.**

STORING AND DISPOSING OF VOLUVEN

Store at or below 25 ºC

Do not freeze.

KEEP OUT OF REACH OF CHILDREN.

Do not use Voluven after the expiry date which is stated on the label.

Your doctor or nurse will ensure that the solution is clear, free from visible particles, the container is undamaged and the overwrap is removed from the Freeflex® bag before use.

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

PRESENTATION OF VOLUVEN

It is presented in 250 ml and 500 ml bags. The bags are made of Freeflex®, with or without overwrap, or PVC with overwrap.

IDENTIFICATION OF VOLUVEN

Voluven is a sterile, clear solution and is free from visible particles.

REGISTRATION NUMBER

34/8.4/0417

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Fresenius Kabi South Africa (Pty) Limited

Stand 7, Growthpoint Park

2 Tonetti Street

Halfway House

1685

South Africa

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