

The use of Voluven in critically ill patients, including those with severe sepsis, is associated with an increased risk of death or the need for renal replacement therapy.

# Voluven<sup>®</sup> 6%

Hydroxyethyl Starch 130/0.4 in a balanced electrolyte solution

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Voluven. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you given Voluven against any benefits they expect it will have for you.

**Please read this leaflet carefully. If you have any questions or are unsure about anything, please ask your doctor or pharmacist.**

**Keep this leaflet. You may need to read it again.**

### What is Voluven used for

Voluven 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. It is not a substitute for blood or blood containing products.

### Before you are given Voluven

You must NOT use this product if you:

- are critically ill to be admitted to intensive care unit.
- are allergic to hydroxyethyl starches or any of the other ingredients as listed at the end of this leaflet.

- have bleeding of the brain

(cerebral haemorrhage)

- have too high sodium or chloride levels in your blood
- have a severe blood infection
- have severe liver disease
- have coagulation or bleeding disorder
- have been told that you have pulmonary oedema where too much fluid is in your lungs
- have been told that you have a congestive heart failure (a condition in which your heart cannot pump enough blood to other organs of your body)
- have kidney failure and you produce little or no urine and if this is not caused by low blood volumes (hypovolemia)
- are receiving dialysis treatment (an artificial kidney treatment)

Before you use Voluven, you must also tell your doctor if you have problems with your heart, liver, lung or have severe lack of fluid (dehydration). Special care has to be taken while this product is given to you. Infusion of large quantities of plasma substitutes may cause too much dilution of blood components or blood clotting factors and blood samples may be taken to check this.

If you have impaired kidney function, your doctor will need to adjust the dosage since Voluven is excreted by the kidneys.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

The safety of the product in pregnant and breast-feeding

women has not been investigated.

### How Voluven is given

#### *How much will be given*

Your doctor will determine the amount of Voluven that is appropriate for you.

#### *How is it given*

Voluven should be administered by continuous drip into the vein using a sterile tubing and needle. It should only be administered to you by qualified medical staff. You will be kept under close observation by a health professional at the beginning of Voluven infusion to ensure that you do not have an allergic reaction as all plasma substitutes carry a slight risk of allergic reactions that can be mild or severe.

#### *If you are given too much (overdose)*

This rarely happens as Voluven is usually administered under the care of a trained health care professional in a hospital or clinic setting.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Otherwise immediately telephone your doctor or contact the Poisons Information Centre in your country.

Australia: 13 11 26  
New Zealand: 0800 764 766.

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## Side Effects

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Voluven, like all other medicine which are given intravenously, may cause unwanted effects in some people.

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- mild flu-like symptoms
- itching of the skin

**Tell your doctor as soon as possible if you notice any of the following:**

- serious allergic reactions (skin rash and hives)
- breathing difficulties (wheezing or coughing)
- effects on heart beat (slower or faster than normal)

**Please tell your doctor or your health professional if you feel unwell during treatment.**

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## Storage

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Voluven should be stored below 25°C and not be frozen. As with any medicine, Voluven should be stored out of the reach of children. Do not use injections that have been used, have expired or the container is damaged.

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## Product Description

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### ***What it looks like***

Voluven 6% is a clear, colourless solution which comes in a glass bottle or plastic bag.

### ***Ingredients***

Voluven contains hydroxyethyl starch 130/0.4 and also contains excipients sodium chloride.hydrochloric acid, sodium hydroxide and water for injections.

Voluven does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes. Voluven does not contain any preservative.

Voluven comes in 2 different containers and 2 pack sizes. They can be identified by the following AUST R numbers:

Glass bottles 250ml  
AUST R 120276

Glass bottles 500ml  
AUST R 120358

Freeflex<sup>®</sup> bags with overwrap  
250 mL  
AUST R 120359

Freeflex<sup>®</sup> bags with overwrap  
500 mL  
AUST R 120361

### **Further Information**

More detailed information is available from your doctor or pharmacist.

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## Sponsor

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### ***Date of information***

This information leaflet was prepared in August 2016.