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

Volulyte® 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 Volulyte. 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 Volulyte 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 Volulyte 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. It is not a substitute for blood or blood containing products.

Before you are given Volulyte

You must NOT use this product if you:

- are critically ill to be admitted to intensive care unit.
- have too much fluid in your body and you have been told that you have a condition known as hyperhydration
- 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)
- suffer from bleeding within or around the brain (intracranial bleeding)
- are allergic (hypersensitive) to hydroxyethyl starch or any of the other ingredients.
- have coagulation or bleeding disorder
- have severe liver disease
- have too high sodium, potassium or chloride levels in your blood
- have a severe blood infection

Your doctor may need to take special precautions and will decide whether you can receive Volulyte if you suffer from:

- problems with your heart or kidneys as there is an increased risk of fluid overload with the use of Volulyte
- a severe lack of fluid (dehydration). In this case your doctor should administer a salt solution first

Before you use Volulyte, you must also tell your doctor if you have problems with your heart, liver or lung. 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 Volulyte is excreted by the kidneys

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

The safety of the product in pregnant and breast-feeding women has not been investigated.

How Volulyte is given

How much will be given

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

How is it given

Volulyte 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 Volulyte 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 Volulyte 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.

Side Effects

Like all medicines, Volulyte can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nursing staff immediately:

Rare (occurring in more than 1 in 10,000 patients, but less than 1 in 1,000 patients)

- 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.

Common (occurring in more than 1 in 100 patients, but less than 1 in 10 patients)

- 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 and its components, 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, hydroxyethyl starch does not cause pancreatitis.

If you have any unexpected effects after receiving Volulyte, or you feel unwell during treatment, contact your doctor or pharmacist.

Storage

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

Product Description

What it looks like

Volulyte 6% is a clear to slightly opalescent, colourless to slightly yellow solution which comes in a plastic bag.

Ingredients

Volulyte contains the active ingredients Hydroxyethyl starch 130/0.4, Sodium chloride, Sodium acetate trihydrate, Potassium chloride and Magnesium chloride hexahydrate.

It also contains other inactive ingredients such as hydrochloric acid, sodium hydroxide and water for injections.

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

Volulyte does not contain any preservative.

Volulyte comes in 2 different sizes of plastic (**free***flex*®) bag.They can be identified by the following AUST R numbers:

free*flex*® bags 250 mL
AUST R 172173
free*flex*® bags 500 mL
AUST R 187473

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about Volulyte please ask your doctor or pharmacist.

Sponsor

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way,
Mount Kuring-gai
NSW 2080
Australia
Telephone: 1300 361 004

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall Telephone: 0800 144 892

® = Registered Trademark

Date of information
This information leaflet was prepared in August 2016.