# APPROVED PATIENT INFORMATION LEAFLET

## VOLULYTE®

## Scheduling status

S3

## Proprietary name and dosage form

**Volulyte®,** solution for infusion

Hydroxyethyl starch (HES 130/0,4) in a balanced, isotonic electrolyte solution

## Read all of this leaflet carefully before you receive Volulyte

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

***The active ingredients are (per 1 000 ml):***

Poly(O-2-hydroxyethyl) starch 60,00 g

- Molar substitution 0,38 - 0,45
- Mean molecular weight ($M_w$) 130 000 Da

| | |
|---|---|
| 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 |
| Titratable acidity | < 2,5 mmol NaOH/l |
| pH | 5,7 - 6,5 |

***The other ingredients are:*** Sodium hydroxide, hydrochloric acid (25 %), and water for injections.

## WHAT VOLULYTE IS USED FOR

Volulyte 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).

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

## BEFORE YOU RECEIVE VOLULYTE

### You should not be administered Volulyte if:

- you are allergic (hypersensitive) to hydroxyethyl starch (see POSSIBLE SIDE EFFECTS) or any of the other ingredients of Volulyte.
- you are critically ill with or without blood infections/blood poisoning (sepsis/septicaemia)
- you have severe burns
- your kidneys do not work well
- you suffer from kidney failure and you produce little or no urine
- you have lost too much fluid (moderate to severe dehydration)
- you have severe liver problems
- 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 are receiving dialysis treatment (an artificial kidney treatment)
- you have very high levels of potassium, sodium or chloride in your blood (severe hyperkalaemia, severe hypernatraemia or severe hyperchloraemia)
- you already have blood clotting (coagulation) or bleeding disorders
- you suffer from bleeding within or around the brain (intracranial bleeding).

## Take special care with Volulyte

### *Tell your doctor or healthcare professional before being given Volulyte*

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 Volulyte if you suffer from:

- Problems with your circulation, heart or kidneys, as there is an increased risk of fluid overload with the use of Volulyte.
- Increased levels of potassium, sodium or chloride levels in your blood (hyperkalaemia, 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 Volulyte.

## Receiving Volulyte with food and drink

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

## Pregnancy and breastfeeding

The safety of Volulyte in pregnant women has not been established.

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

## Driving and using machinery

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

## Taking other medicines with Volulyte:

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

The use of Volulyte with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Volulyte is not known to have any interactions with other medicines.

## HOW TO RECEIVE VOLULYTE

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

You will not be expected to give yourself Volulyte.

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

## Mode of administration:

You will receive Volulyte 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 the product 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.

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

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

## If you have received more Volulyte than you should:

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

## POSSIBLE SIDE EFFECTS

Volulyte can have side effects.

Not all the side effects reported for Volulyte are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving Volulyte, please consult your doctor, pharmacist or other healthcare professional for advice.

## The following symptoms are very serious; you must contact your doctor immediately if you have any of these:

- Volulyte may lead to anaphylactic/anaphylactoid reactions. These are severe allergic reactions (reddening of the skin, swelling of the throat, and difficult 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 Volulyte. You may need urgent medical attention and further hospitalisation.

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

***Frequent side effects:***

- Itching
- Other effects are associated with the dilution of the blood such as prolonged blood clotting time or bleeding.
- Increased serum amylase during administration of Volulyte, which may interfere with the diagnosis of inflammation of the pancreas (pancreatitis).

***Less frequent side effects:***

- After administration of Volulyte, disturbances of blood clotting beyond effects caused by dilution of your blood can occur. If this occurs, the infusion will be stopped and appropriate treatment will be given.

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

**STORING AND DISPOSING OF VOLULYTE**

Store at or below 25 ºC.

Do not freeze.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

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

Your doctor or nurse will ensure that the solution is clear, free from particles, the container 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 container is for single use only.

## PRESENTATION OF VOLULYTE

It is presented in 500 ml flexible bag made of polyolefin (freeflex®). The bags are clear in colour. The freeflex® packaging system consists of a primary container (foil and tubing), administration port, and an overwrap. Packed in 1's; 10's; 15's; 18's and 20's.

## IDENTIFICATION OF VOLULYTE

Volulyte is a sterile, clear to slightly opalescent solution, colourless to slightly yellow. The solution is free from particles that can be observed on visual inspection.

## REGISTRATION NUMBER

41/8.4/0211

## NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE

Fresenius Kabi South Africa (Pty) Limited

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## DATE OF PUBLICATION

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