

## PATIENT INFORMATION LEAFLET

### Contraindications

Should not be used in patients with sepsis, renal failure or in critical conditions.  
Please see Section 4.3.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You may help by informing any adverse reaction.

### **VOLUHES (HES 130/0.4) 6% Solution for i.v. infusion**

**For intravenous use.**

**Sterile**

- **Active ingredient:** Hydroxyethyl starch (HES 130/0.4), Sodium chloride
- **Excipients:** Sodium hydroxide, Hydrochloric acid, water for injection

**Please read this PATIENT INFORMATION LEAFLET carefully before starting to use the drug; because important information is included here.**

- *Keep this PATIENT INFORMATION LEAFLET. You may need to re-read it later.*
- *In case you have additional questions, please consult your doctor or pharmacist.*
- *This drug is prescribed personally for you, do not give to others.*
- *During the use of this drug, please tell your doctor that you are using this drug when you visit your doctor or a hospital.*
- *Please follow these instructions strictly. Do not use dosages **higher or lower** than the dosage recommended to you.*

### **The following headlines are included:**

- 1. What is VOLUHES and what it is used for?*
- 2. Before you are given VOLUHES*
- 3. How you will be given VOLUHES?*
- 4. Possible side effects*
- 5. How to store VOLUHES*

#### **1. What is VOLUHES and what is it used for**

- VOLUHES, including hydroxyethyl starch, and sodium chloride for the active substances, it is a sterile (aseptic) solution and intended for intravenous use.
- VOLUHES is a clear or slightly opaque, colorless or light yellow solution which is presented in 500 ml PP bags.
- VOLUHES is used to complete the blood volume when you lose blood and crystalloid other products are not enough alone.

## **2. Before you are given VOLUHES**

### **DO NOT USE VOLUHES under the following conditions**

- If you are allergic (hypersensitive) to hydroxyethyl starch or any of the other ingredients.
- If you have severe infection (sepsis)
- If you are suffering from burn injuries
- If you have kidney failure and you are receiving dialysis treatment (an artificial kidney treatment)
- If you suffer from bleeding in the brain (intracranial bleeding)
- If you are critically ill (for example, you need to stay in the intensive care unit)
- If you have too much fluid in your body and you have been told that you have a condition known as hyperhydration
- If you have been told that you have pulmonary oedema where too much fluid is in your lungs
- If you are dehydrated.
- If you have severe increased sodium or chloride levels in your blood (hypernatraemia, hyperchloraemia)
- If you have severely impaired liver functions.
- If you have been told that you have congestive heart failure (a condition in which your heart cannot pump enough blood to other organs of your body)
- If you have serious problems with clotting of the blood
- If you have had an organ transplant.

### **USE VOLUHES with CAUTION if**

- You have deterioration in liver function.
- You have problems with our heart or circulatory system.
- You have any discomfort about blood clotting (coagulation).
- You have problems regarding your kidneys.

Allergic (anaphylactic/anaphylactoid) reactions due to the risk of an allergic reaction to this medicine is taken will be monitored closely to detect early signs.

Surgery and trauma:

Your doctor will evaluate carefully whether this medication is right for you.

Your doctor will adjust the dose of VOLUHES carefully to avoid fluid overload. This is especially done if you have problems with your lungs, your heart or circulatory system. Nursing staff is also the fluid balance of the body, it will take measures to monitor the level of salt in the blood and kidney function. If necessary, you can get additional salts.

In addition, you will be getting enough fluids.

If you have kidney damage causing renal failure or dialyses do not use VOLUHES.

If impairment of renal function occurs during treatment:

If your doctor detects the first signs of kidney disorders will you stop this medicine. In addition, your doctor may need to monitor your kidney function for 90 days.

If you are given VOLUHES repeatedly the ability to clot forms, bleeding time and other blood functions will be followed by your doctor. If you have a disorder about ability to clot form, your doctor will stop giving you VOLUHES.

If you're going into open heart surgery and a heart-lung machine is connected to help your blood pumping, during the implementation, this solution is not recommended.

These warnings at any time in the past, though, even if true for you, please consult your doctor.

### **Using VOLUHES with food and beverages**

VOLUHES is not known to have any negative effect when given at the same time as food or drink.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

There is no data on the use of product for pregnant (except for cesarean surgery, see below). Animal studies pregnancy, embryo/fetal development, does not indicate direct or indirect harmful effects on the birth or postnatal development. No evidence of teratogenicity was seen.

Pregnant women undergoing cesarean section with spinal anesthesia, there is limited clinical trial data on the use of single-dose VOLUHES. The negative effect of VOLUHES on patient safety has not been determined; also it has not been detected a negative effect on the newborn.

For VOLUHES no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or postnatal development. No evidence of teratogenicity was seen.

There are limited clinical study data available from the use of a single dose of VOLUHES in pregnant women undergoing Caesarean section with spinal anesthesia. No negative influence of VOLUHES on patient safety could be detected; a negative influence on the neonate could also not be detected.

VOLUHES should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

*In case you become aware that you are pregnant during treatment, immediately consult your doctor or pharmacist.*

### **Lactation**

*Consult your doctor or pharmacist before using this drug.*

There are currently no clinical data available on the use of VOLUHES in lactating women. Hydroxyethyl starch excreted in human milk is not known. Hydroxyethyl starch transition to milk has not been studied in animals. If you are breastfeeding, your doctor will decide continue to breastfeed/or not to continue, continue to treatment with VOLUHES/or not to continue treatment with VOLUHES, taking into account the benefits of breastfeeding to your child and benefits of VOLUHES will give you.

### **Vital information regarding some of the excipients contained in VOLUHES**

This medicine contains 154 mmol sodium (3.54 g) per 1000 ml. In this case, control should be considered for patients with sodium diet.

### **Ability to drive and use machines**

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

### **Use in combination with other drugs**

VOLUHES does not have any known interaction with other drugs.

*If prescribed or non-prescribed medication you are currently using or have used recently, please give the information to your doctor or pharmacist.*

## **3. How you will be given VOLUHES?**

- **Instructions regarding correct use and dosage/administration frequency:**

Your doctor will decide on the correct dose for you to receive.

***Doctor will use the lowest possible effective dose and will not infuse VOLUHES more than 24 hours.***

The maximum daily dose is 30 ml/kg for 6% HES (130/0.40) and 6% HES (130/0.42). The maximum daily dose should be recalculated for other HES products.

### **Method 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.

### **Use in children:**

There is only limited experience on the use of this medicine in children. Therefore, this drug is not recommended for use in children.

### **Special cases:**

**Kidney failure:** Should not be used patients with kidney failure and patients receiving dialysis.

**Liver failure:** Should not be used in patients with severe liver disease.

*If you have the impression that it is too strong or too weak effect of the VOLUHES talk with your doctor or pharmacist.*

**If you have taken more VOLUHES than you should have:**

*If you have used VOLUHES more than you should have or more than prescribed, consult a physician or a pharmacist.*

As with all drugs complete volume, if you have received too much VOLUHES there could be problems such as water retention in your lungs (pulmonary edema) that could cause the circulatory system overload.

Your doctor will ensure that you receive the right amount of VOLUHES. However, different people need different doses, and if the dose does prove too much for you, your doctor may stop VOLUHES immediately and, if necessary, administer a medicine that removes water from the body (diuretic).

**If you forget to take VOLUHES:**

*Do not take a double dose to make up for the forgotten dose.*

**Possible effects once VOLUHES treatment is concluded:**

None.

**4. Possible side effects**

Like all medicines, VOLUHES 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.

The frequency of side effects is classified into the following categories:

Very common: in more than 1 in 10 patients

Common : in more than 1 in 100 patients, but less than 1 in 10 patients

Uncommon : in more than 1 in 1,000 patients, but less than 1 in 100 patients

Rare : in more than 1 in 10,000 patients, but less than 1 in 1,000 patients

Very rare : in less than 1 in 10,000 patients, including isolated reports

**Common:**

- Itching
- 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, VOLUHES does not cause pancreatitis.
- Dilution effect of high doses of plasma proteins such as coagulation factors and other blood components, and the corresponding dilution of the blood volume to volume ratio of the sum formed by red blood cells (hematocrit) would result in a decrease

**Rare:**

- Disorders related to blood coagulation

- 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).

**Unknown (cannot be estimated from the available data):**

- Liver failure
- Kidney failure

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

**5. How to store VOLUHES**

*Keep out of the reach and sight of children and store in package.*

*Keep at temperatures under 25°C, protect from light, do not freeze.*

**Use in accordance with expiration dates.**

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

*Do not throw away expired or remained products! Please follow the local regulations.*

***Marketing Authorization Holder and Manufacturing Site:***

POLİFARMA İLAÇ SAN. VE TİC. A.Ş.

Vakıflar OSB Mahallesi, Sanayi Caddesi, No:22/1 Ergene/Tekirdağ/TURKEY

Tel: +90 282 675 14 04

Fax: +90 282 675 14 05

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**THE FOLLOWING INFORMATION IS FOR THE HEALTHCARE PERSONNEL WHO WILL ADMINISTER THIS DRUG**

**Hydroxyethyl starch (HES) use with maximum 24-hour period must be limited in the initial phase of volume resuscitation.**

- The recommended maximum daily dose is up to 30 ml of VOLUHES per kg of body weight.
- Dose should be administered at the lowest possible daily dose. The achievement of hemodynamic goals of treatment should be continued with continuous hemodynamic monitoring to stop the infusion inaccessible.
- The maximum recommended daily dose should not be exceeded.
- The initial 10-20 ml are to be infused slowly, keeping the patient under close observation due to possible anaphylactic/anaphylactoid reactions.
- If an anaphylactoid/anaphylactic reactions occur if the infusion should be discontinued immediately and appropriate emergency medical treatment should be 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.).

**Treatment of children**

There is only limited experience on the use of this medicine in children. Therefore, this drug is not recommended for use in children.

For single use only.

To be used immediately after first opening.

Any unused solution should be discarded.

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

Remove the overwrap from the PP bag prior to use.

**Instructions for use**

**How to open:**

1. Check the intactness of the outer packaging and if there is any leakage; do not use the packaging if the packaging is damaged.
2. Tear off the protective outer packaging.
3. Check if the bag within the protective packaging is intact.
4. Check the clarity of the solution within the bag and there is no foreign material within.

**Preparations for the administration:**

1. Hang the bag.
2. Remove the protective cap at the application tip.

3. Stab the spike of the application set to the application tip tightly. The instructions for use of the set must be followed when administering solution to the patients.

**Mixing additional drugs:**

**Caution:** Like all the parenteral solutions, all the substances to be added to the product must be compatible with the product. If any drug will be added to the solution, compatibility in the final mixture must be checked before administration to the final mixture.

***Addition of drugs before administration***

1. The administration end will be disinfected.
2. The drug to be added will be added into the bag using an injector with a 19-22 gauge tip.
3. The solution with the added drug will be mixed thoroughly. For drugs with high density like potassium chloride, mixing will be ensured by tapping the application outlet of the bag gently when it is in the upside position.

***Mixing drugs during administration***

1. The clamp of the set will be closed.
2. The administration end will be disinfected.
3. The drug to be added will be added into the bag using an injector with a 19-22 gauge tip.
4. Solution is removed from the hanger and turned upside down.
5. In this position, mixing of the added drug and the solution will be ensured by tapping the administration end and the injection input gently of the bag.
6. The bag will be brought to the previous position and administration will be continued.