PATIENT INFORMATION LEAFLET

VOLİZOLEN (HES 130/0.4) 6 % electrolyte solution for I.V. infusion

For intravenous administration.

Sterile,apyrogen

Active substances: Each 100 ml solution contains 6 g hydroxyethyl starch, 0.602 g sodium chloride, 0.463 g sodium acetate trihydrate, 0.03 g potassium chloride, 0.03 g magnesium chloride hexahydrate.

Excipient(s)**:** sodium hydroxide, hydrochloric acid, water for injection.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4 for how to report adverse reactions.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow the written instructions exactly. Do not use* ***higher or lower*** *dose than the recommended dose.*

The following subjects are covered herein:

1. What is *VOLİZOLEN* and what is it used for?

VOLİZOLEN is a sterile apyrogen solution prepared for intravenous administration. It contains active ingredients called hydroxyethyl starch, sodium chloride, sodium acetate trihydrate, potassium chloride and magnesium chloride hexahydrate. Solution of 500 milliliters

Available in PP bags. It belongs to a group of drugs known as plasma volume expanders. It acts by increasing blood volume and maintaining circulation. It helps to keep blood pressure constant.

- VOLİZOLEN is used when:

- In the treatment and prevention of low blood volume (hypovolemia)

-Protection of blood volume during surgical procedures

2. Before you are given *VOLİZOLEN*?

DO NOT USE *VOLİZOLEN* under the following circumstances

If;

- Allergy to excessive hydroxyethyl starch or other substances in the drug (excessive sensitivity)
- When the amount of blood or fluid in the body increases (hypervolemia and hyperhydration)
- Severe heart disease with fluid accumulation in the body (congestive heart failure and decompensated heart failure)
- Heavy kidneys with decreased urine output or no urine output patients undergoing disease and dialysis
- Dialysis treatment (artificial kidney treatment)
- Intracranial hemorrhages or cerebral hemorrhage
- Lung disease (fluid edema) with fluid accumulation in the lungs
- Severe general infection (sepsis)
- Severe liver disease
- The amount of sodium or chlorine in the blood increases too much (advanced hypernatremia or hyperchloraemia)
- In case of burns
- If you are in a group that is classified as a critical patient (usually in the intensive care unit patients)
- Dehydration status (severe water loss in the body)
- If there are serious coagulation disorders

- You have had an organ transplant.

Take special care with *VOLİZOLEN* in following conditions

If;

- Heart disease
- Kidney disease
- Liver diseases
- Allergic (hypersensitivity) diseases (See side effects related to sudden hypersensitivity response.)
- Some conditions in which the amount of minerals in the blood are increased (hypernatremia, hyperkalaemia, hypermagnesemia, hyperchloremia)
- Severe bleeding conditions (such as von Willebrand disease)

It is important to support a sufficient amount of fluid and regularly monitor kidney function and fluid balance. Your doctor will balance you with fluid and salt during application, will follow in terms of kidney function. The application should be stopped at the first sign of kidney damage.

In general, excessive fluid overload caused by overdose should be avoided. Especially in patients with severe renal dysfunction (dysfunction) or heart failure an increased risk of hyperhydration (increased fluid volume) should be considered and dose adjusted.

Your doctor should first give a crystalloid solution in cases of severe dehydration.

Surgery and trauma:

Long-term safety studies in patients with ongoing surgery and trauma have shown a weakness. The expected benefits of treatment should be carefully measured against the potential risk resulting from this long-term safety study. Other treatment options will be evaluated by your doctor.

In critical patients, crystalloids should be used primarily, and VOLİZOLEN should only be used if the crystalloids are insufficient to stabilize patients and the expected benefit outweighs the risk.

Dose reduction in critical patients, the actual needs of the patient and the severity of the disease should be taken into consideration by your doctor, and the minimum effective dose should be given.

Special care should be taken by your doctor in patients with pulmonary edema or severe bleeding disorders (eg severe von Willebrand disease). If your doctor treats patients with increased blood or fluid in the body (hypovolemic), with severe hemodilution.
High doses of HES solutions should be avoided (as it may result in increased plasma volume in the blood compared to erythrocytes, watering the blood).
In case of repeated application, blood clotting (coagulation) values should be carefully monitored by your doctor.
The use of HES should be stopped by your doctor at the first sign of blood clotting disorder.
It is not recommended to use products containing HES during open heart surgery associated with cardiopulmonary bypass as it may cause excessive bleeding.
Your doctor will follow you closely against the risk of hypersensitivity (anaphylactic / anaphylactoid) and start the application at low speed.
An increase in the need for kidney support (renal replacement) treatment has been reported within 90 days of HES application. Your doctor will monitor your kidney function for at least 90 days.

If these warnings were experienced by you, even at any time in the past, please contact your doctor.

Use of *VOLİZOLEN* with food and drink

VOLİZOLEN is administered intravenously; there is no interaction with food and drinks in terms of its route of administration.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

There are no clinical data on the use of VOLİZOLEN in pregnant women.
VOLİZOLEN should be used if the potential benefit / loss assessment that may occur in the fetus during pregnancy results positively. Your doctor will give you the drug if he / she deems it appropriate after making a benefit-loss assessment. VOLİZOLEN should not be used during pregnancy unless necessary.

If you notice that you have been pregnant during treatment, tell your doctor or pharmacist immediately.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

No research has been conducted on the use of VOLİZOLEN in breastfeeding individuals. Your doctor will give you the medicine if he / she deems it appropriate after making a benefit-loss assessment.

Driving and using machinery

It is not possible to drive and use machines for patients taking VOLİZOLEN.

Important information on some excipients present in VOLİZOLEN

If you are not sensitive to the excipients in the content of VOLİZOLEN, a negative effect due to these substances is not expected.

This medicinal product contains 6.02 g (103 mmoL) of sodium per 1000 ml. This should be considered for patients on a controlled sodium diet.

Taking with other medicines

VOLİZOLEN has no drug interactions known yet. For hydroxyethyl starch, elevated serum amylase concentration that may increase during administration and affect the diagnosis of pancreatitis please refer to "possible side effects" section.

Since VOLİZOLEN also acts on blood clotting, you should inform your doctor, especially if you are using it to prevent blood clotting or if you are taking medicines that thin your blood (for example, heparin, warfarin, pain relievers called NSAIDs, sodium valproate) used in epilepsy.

Care should be taken when applying with drugs that can cause potassium or sodium retention in your body.

Please inform your doctor if you plan, are taking, or have recently taken any other medicines, including over-the-counter medicines, vaccines, and herbal medicines.

It should be avoided by mixing with other drugs. In cases where it should be mixed with other medicines, it should be ensured that it is compatible (cloudiness, collapse), hygienic injection and a good mixture.

If you are taking or have recently taken any other medicines, with or without a prescription, tell your doctor or pharmacist.

3. How you will be given VOLİZOLEN?

Instructions regarding correct use and dosage/administration frequency:

The dose to be given depends on other factors such as your health condition and weight.

Your doctor will determine the dose of your medicine and apply it to you depending on your illness. The recommended daily maximum dose is 50 milliliters per kilogram.

Route and method of administration:

It is applied through a small tube placed in the veins. The infusion rate is determined by reference to the maximum dose per day, based on the amount of infusion solution and which disease it is used for.

- **Different age groups**

Use in children:

HES products are not recommended for use in children since data is limited in children.

Elderly:

It is used as in adults.

- **Special conditions of use:**

Renal/Hepatic impairment:

Patients with renal and hepatic impairment should not use.

If you have the impression that the effect of VOLİZOLEN is too strong or weak, talk with your doctor or pharmacist.

If you have taken more VOLİZOLEN than you should have:

Your doctor will ensure that you are given the correct dose of medication. However, different doses may be required for different individuals. In this case, if the dose is too much for you, your doctor can stop using the drug immediately and apply another drug (diuretic) to remove the water in your body if necessary.

Tell your doctor or pharmacist if you use more VOLİZOLEN than you should.

If you forget to take VOLİZOLEN?

This section does not apply as VOLİZOLEN will be administered to you under medical supervision.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking VOLİZOLEN

There is no data available.

4. Possible side effects

Like all medicines, side effects can occur in people sensitive to the ingredients of VOLİZOLEN. Serious side effects have been reported such as increased use of mortality (death) and renal replacement therapy in individuals with critical illness, including patients diagnosed with VOLİZOLEN, sepsis (severe widespread infection).

Side effects are classified as shown in the following categories:

Very common : It can be seen in at least one of 10 patients.

Common : Less than one in 10 patients, but more than one in 100 patients.

Uncommon : Less than one in 100 patients, but more than one in 1,000 patients can be seen.

Rare : Less than one in 1,000 patients.

Very rare : Less than one in 10,000 patients can be seen.

Unknown : It cannot be estimated from the available data.

Very common:

- Serum amylase (an enzyme involved in starch digestion) increase in enzyme level
- Reduction in protein concentration and hematocrit (ratio of blood cell volume to whole blood volume) due to blood thinning

Common:

- Itching (the result of prolonged and high-dose hydroxyethyl starch)
- High doses cause dilution of clotting factors and this may affect blood clotting. After administration of high doses and blood coagulation time aPTT prolongation (used in the diagnosis of blood coagulation disorders), and a decrease in the concentration of FVIII / vWF (blood clotting elements) can be observed.

Rare:

- Serious allergic (hypersensitivity) reactions (redness of the skin, fever, low blood pressure, redness of the skin, facial flushing, headache, swelling in the throat, difficulty breathing, rapid or slow heartbeat, mild fluid from non-heart-induced lungs flu-like effects)
- Blood clotting disorders (depending on the dose)

Unknown:

- Liver damage
- Kidney damage

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

5. How to store VOLİZOLEN?

Store VOLİZOLEN in packaging and keep out of the reach and sight of children.

Store at temperature below 25°C. Do not freeze.

For single use only.

Partially used bags should not be stored; It must be disposed of in accordance with the medical waste procedures of the health institution where the application is carried out. The bag should be used immediately after opening. Do not use if the solution is cloudy or the packaging is damaged.

Use in compliance with the expiry date.

Do not use VOLİZOLEN after the expiry date on the packaging.

Marketing Authorisation Holder and Manufacturing Site:

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