Package leaflet: Information for the user

Sodium Chloride Grifols 0.9% w/v

Solution for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
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1. What Sodium Chloride Grifols 0.9% w/v is and what it is used for

Sodium Chloride Grifols 0.9% w/v belongs to the group of medicines named intravenous solutions affecting the electrolyte balance – electrolytes (used to keep the body fluids in the right balance). This medicine supplies sodium, chloride (both electrolytes) and water, and is indicated for:
- Dehydration states with salt loss
- Hypochloremic metabolic alkalosis
- The management of hypovolaemia (a decrease in the amount of body blood)
- As a vehicle for the administration of compatible drugs and electrolytes.

2. What you need to know before you use Sodium Chloride Grifols 0.9% w/v

Do not use Sodium Chloride Grifols 0.9% w/v:
- if the levels of chlorides and/or sodium in your blood are high (hyperchloraemia and hypernatraemia respectively) or if you suffer from hypernatraemia (excess of water in your body)
- if you suffer from acidosis (level of pH lower than normal range)
- if you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Warnings and precautions
Sodium Chloride Grifols 0.9% w/v is an isotonic solution.

Talk to your doctor or nurse before using Sodium Chloride Grifols 0.9% w/v. This medicine should be administered with caution if you suffer from hypotension including pre-eclampsia (development of hypertension during pregnancy/eclampsia (complication of severe pre-eclampsia), congestive heart failure, pulmonary or peripheral edema, severe renal insufficiency, decompensation cirrhosis (liver disease with life-threatening symptoms and complications), primary hyperaldosteronism (excessive production of the hormone aldosterone) as well as if you are receiving corticosteroids or adrenocorticotropic hormone (hormone that stimulates the secretion of cortisol and other steroid hormones) (see next subsection).

This medicine should be administered with caution if the levels of potassium in your blood are low (hypokalaemia) because pre-existing electrolyte imbalance may get worse leading to cardiovascular complications, especially if you suffer from heart problems.

It is also should be administered with special care if you are elderly because you may have problems with your heart and kidneys.

During prolonged therapy, or whenever your doctor deems necessary, as in case of existing or imminent acid-base imbalance, periodic monitoring of the fluid balance, serum electrolyte concentrations, and acid base balance must be performed.

Sodium re-equilibration should not be performed at a too rapid rate, especially due to the risk of occurrence of serious neurological complications such as osmotic demyelination syndrome (brain disease caused by severe damage of the myelin sheath of brain cells) (see section 4). This medicine should be administered only for short period therapy as a prolonged administration could lead to a metabolic acidosis.

Because of the administration technique, you may experience extravasation (a discharge or escape of fluid from a vein into the tissues) and/or thrombophlebitis (inflammation of the vein with clot formation) during intravenous infusion (see section 4). Extravasation may lead to tissue damage (focal pain, erythema, burning, itching, swelling and ulceration) at the site of injection or along the vein. Thrombophlebitis might occur if the administration in the same site of injection is prolonged. In these cases, your doctor or nurse should stop the intravenous infusion and institute appropriate therapeutic measures. They must check periodically possible signs of inflammation at the injection site.

Due to the risk of air embolism (when one or more gas bubbles enter a vein or artery) your doctor or nurse must take particular care in the handling of the administration sets.

When adding a medicinal product to the solution, your doctor or nurse must check compatibility, clarity and colour before use. The medium cannot be stored.

Children and adolescents
In premature and breast-feeding neonates, sodium chloride administration should only be performed after determining sodium levels in blood. There are no other specific warnings or precautions to children and adolescents.

Other medicines and Sodium Chloride Grifols 0.9% w/v

Some medicines may interact with Sodium Chloride Grifols 0.9% w/v. In this case, a change of dosage or a treatment disruption of some of the medicines might be required.

It is important to tell your doctor if you are using some of the following medicines:
- Lithium carbonate, since the administration of sodium chloride accelerates renal lithium secretion, leading to a decrease in the therapeutic action of lithium.
- Corticosteroids or adrenocorticotropic hormone, since they favour water and sodium retention.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

There is no evidence indicating that maternal infusion of sodium chloride 0.9% during pregnancy has any harmful effects on the fetus or the newborn.

Precautions must be taken during pregnancy in pre-eclampsia situations (see Warnings and precautions).

Sodium chloride is excreted in human milk but taking into account that it is a natural constituent of human milk, no side effects on the breastfed infant are expected following maternal intravenous administration of therapeutic doses. Nevertheless, it is recommended to use with caution during these periods.

There are no data regarding fertility and use of sodium chloride solutions but no side effects are anticipated.

When this medicine is used as a vehicle for the administration of compatible drugs and electrolytes, the nature of the additive and its use during pregnancy and lactation should be evaluated separately.

In any case, the doctor must evaluate if the treatment is advisable.

Driving and using machines

Not relevant.

3. How to use Sodium Chloride Grifols 0.9% w/v

This medicine will be administered by healthcare professionals.

It is intended for intravenous administration by means of infusion.

Your doctor will decide the amount of fluid and the rate and duration of the infusion that you should receive depending on your age, weight and medical condition.

In general, it is recommended to administer the solution at an average infusion rate of 40 to 60 drops per minute (120-180 mL/h). When administering this solution, the total daily fluid requirement must be considered. The daily recommended dose of fluid is the following:

- adults: between 25-35 mL/kg
- children: – less than 10 kg body weight: 100 mL/kg
  - between 10-20 kg body weight: 1000 mL + 50 mL/kg for every kg over 10 kg
  - more than 10 kg body weight: 1500 mL + 20 mL/kg for every kg over 20 kg

In adults, the maximum daily dose of fluid is 40 mL/kg (corresponding to 6 mmol of sodium/kg not exceeding 3000 mL, and the maximum infusion rate is 5 mL/kg/h. Children rarely need more than 2500 mL for males and 2000 mL for females.

In case of acute plasma volume depletion (e.g. imminent or evident hypovolemic shock) the amount of solution should be 3 or 4 times the lost blood volume.

When this medicine is used as a vehicle for the administration of compatible drugs and electrolytes, the administered dosage and the speed of the infusion will depend on the nature and the dose of the prescribed medicinal product.
If you receive more Sodium Chloride Grifols 0.9% w/v than you should
The excessive administration of 0.9% sodium chloride solution may result in fluid overload (hypervolemia, hyperviscosity) and/or salt overload (hypernatremia and hyperchloremia) (see section 4). In these cases, administration should be discontinued and appropriate therapeutic countermeasures should be instituted.

If fluid overload occurs (hypervolemia, hyperviscosity) you may experience pulmonary and/or peripheral edema and their consequent effects (heart failure).

With an excessive intravenous administration of sodium you may develop hypernatremia leading to intracranial dehydration (loss of water from inside to outside the cells that could lead to cellular desiccation), which should be treated in specialized areas. If it occurs you may experience nausea, vomiting, diarrhea, abdominal cramps, thirst, induced salivation and aphonia, fever, tachycardia, headache, dizziness, restlessness, irritability, weakness, (lithypnia transient loss of consciousness), muscular twitching and rigidity, sweating, confusion progressing to convulsions, coma, renal failure, central, peripheral and pulmonary edema, respiratory failure and death.

Serious neurological complications such as osmotic demyelination syndrome (brain damage caused by severe damage of the myelin sheath of brain cells) can occur several days after too important and/or too rapid correction of hypovolemia (see section 4). If it occurs you may experience the following progressive clinical signs: confusion, speech and/or swallowing disorders, weakness of the limbs, tetraplegia, delirium and finally coma.

Excessive administration of chloride may cause hyperchloremia and hence, there is a loss of bicarbonate and acidosis. Often hyperchloremia does not produce any symptoms. In cases where symptoms develop, they are similar to those of hypernatremia.

When this medicine is used as a vehicle for the administration of compatible drugs and electrolytes, other signs and symptoms of excessive injection may arise from the added medicinal product. If it occurs, treatment should be stopped and you should be monitored for any clinical signs and symptoms associated with the medication given. You should receive symptomatic treatment and appropriate support.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Hypervolemia, hypernatremia, hyperchloremia, hyperviscosity (loss of body water, plasma sodium, plasma chloride and blood volume respectively) and related signs, such as thirst, formation of edema (abnormal accumulation of fluid in tissues between the body's cells) or metabolic acidosis due to the decrease of bicarbonate concentration (increase in plasma acidity because there is not enough bicarbonate to effectively neutralize the effects of the acid), may occur following an inadequate or excessive administration of this medicine.

Side effects derived from the prolonged administration by intravenous route in the same infusion site may also occur. These effects include pain or reaction in the injection site, fever, extravasation, venous thrombosis (formation of a blood clot inside a vein obstructing the flow of blood) and phlebitis (inflammation of a vein) extending from the site of injection.

If it is used as a vehicle for the administration of other compatible drugs, other side effects attributable to the nature of these added drugs may also occur.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: https://www.medicines.org.uk or telephone 0800 303 3232. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sodium Chloride Grifols 0.9% w/v

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the solution is not clear or contains particles, or if the container has been damaged.

6. Contents of the pack and other information

What Sodium Chloride Grifols 0.9% w/v contains

The active substance is sodium chloride. Each 100 ml of solution contains 0.9 g of sodium chloride. The other ingredients (preservatives) is water for injections.

The calculated osmolality of the solution is 308 mOsm/L and pH is 4.5-7.0. The theoretical sodium and chloride content is 154 mmol/L.

What Sodium Chloride Grifols 0.9% w/v looks like and contents of the pack

Sodium Chloride Grifols 0.9% w/v is a solution for infusion. It is a clear and colourless aqueous solution.

This medicine is available in polypack/polyethylene flexible bags (Filmddelies) of 500 ml (in boxes containing 20 bags).

Marketing Authorisation Holder and Manufacturer

LAbORATORIos GRIFOLS S.A.
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This medicinal product is authorised in the Member States of the EEA under the following names:

Spain - Chloruro de Sodio Grifols 0.9 %. Solución para perfusión

Czech Republic - Chlórát sodný Grifols 0,9 %

France - Chlorure de Sodium 0,9 % Grifols Solution pour perfusion

Germany - Natriumchlorid Grifols 0,9 % Infusionslösung

Italy - Sodio Chlorato Grifols

Slovakia - Chlórát sodný Grifols 0,9 %

United Kingdom - Sodium Chloride Grifols 0.9% w/v Solution for infusion

This leaflet was last revised in May 2017

Other sources of information

Detailed information on this medicine is available on the web site www.medicines.org.uk

The following information is intended for healthcare professionals only:

Before administration of Sodium Chloride Grifols 0.9% w/v, it must be checked that:

- There is no leakage (by squeezing the bag firmly)
- The solution is clear and without particles.
- Do not administer otherwise (see section 5).
- Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.
- Once the container is opened, the solution must be used immediately.
- To connect the infusion set, separate the protecting tab from the infusion port so that the membrane of access to the bag is exposed. Remove all air from the syringe and associated tubing prior to infusion to avoid air embolism.
- Discard after single use.
- Discard any unused portion.
- Do not reconnect partially used bags.

The compatibility of additives with Sodium Chloride Grifols 0.9% w/v should be checked before administration of a medicinal product.

It is the responsibility of the physician to determine the incompatibility of an additive medicinal product with respect to the Sodium Chloride Grifols 0.9% w/v and the container by monitoring any discoloration and/or formation of precipitates, insoluble complexes or crystals. The instructions for use of the medication to be added must be consulted.

Before adding a medicinal product, verify it is soluble and stable in water at the pH of Sodium Chloride Grifols 0.9% w/v.

When introducing additives to sodium chloride 0.9% solution as well as administering the solution, aseptic technique must be used.

If the solution is not sterile when additives have been introduced.

When a compatible medicinal product is added to Sodium Chloride Grifols 0.9% w/v, the solution must be administered immediately. Do not store solutions containing additives.

This medicinal product is physically incompatible with amphotericin B, an antifungal chemotherapeutic agent.

This medicinal product must not be mixed with other medicinal products unless their compatibility is verified.

Because of the administration technique, extravasation and/or thrombophlebitis may occur during intravenous infusion (see section 4).

In these cases, intravenous infusion should be stopped and appropriate therapeutic measures should be instituted. Possible signs of inflammation at the injection site must be checked periodically.

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