Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sodium Chloride 0.45 % Solution for Infusion

Active substance: sodium chloride

Read all of this leaflet carefully before you are given 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.

This medicine is called `Sodium Chloride 0.45% Solution for Infusion', but will be referred to as `Sodium 0.45 Infusion' throughout the remainder of this leaflet.

What is in this leaflet:

1. What Sodium 0.45 Infusion is and What it is Used For

Sodium 0.45 Infusion is a solution of sodium chloride in water. Sodium chloride is a chemical substance (often called "salt") found in the blood.

Sodium 0.45 Infusion is used to treat:

- a loss of body water, for example after being sick or having diarrhoea (hypertonic extracellular dehydration)
- a lower than normal volume of blood in the body (hypovolaemia)

Sodium 0.45 infusion may also be used to deliver or to dilute other medicines for infusion.

2. What You Need to Know Before You are Given Sodium 0.45 Infusion

Do NOT receive Sodium 0.45 Infusion if you are suffering from any of the following conditions

- lower levels of chloride in the blood than normal (hypochloraemia)
- lower levels of sodium in the blood than normal (hyponatraemia)
- severe kidney problems causing lower than normal or no urine production (oliguria or anuria)
- higher than normal levels of water or sodium in the blood (fluid or sodium retention)
- uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as:
  - shortness of breath
  - swelling of the ankles
- build up of fluid under the skin, affecting all parts of the body (general oedema)
- liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)

If a medicine has been added to Sodium 0.45 Infusion, the Package Leaflet of the added medicine must be consulted to determine whether or not you can receive the solution.

Warnings and precautions

Please tell your doctor if you have or have had any of the following medical conditions:

- any type of heart disease or poor heart function
- poor kidney function
- respiratory failure (lung disease)
  (special monitoring may be required in the above conditions)
- raised production of the hormone aldosterone (aldosteronism)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- high blood pressure (hypertension)
- high blood pressure during pregnancy (pre-eclampsia)

- any other condition associated with sodium and fluid retention (when the body retains too much sodium or water), such as treatment with steroids (See also below "Taking other medicines")
- if you have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body. You may have too much vasopressin in your body because, for example:
  - you have had a sudden and serious illness
  - you are in pain
  - you have had surgery
  - you have infections, burns or brain disease
  - you have diseases linked to your heart, liver, kidneys or central nervous system
  - because you are taking certain medicines (see also below "Other medicines and Sodium 0.45 Infusion").

This may increase the risk of low levels of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death. Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are:

- children
- women (particularly if you are of a fertile age)
- people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury.

Some patients are at higher risk for having or developing a too low sodium concentration in your blood (hyponatraemia). In general this applies to:

- young and old people
- women
- anyone with a condition such as low levels of oxygen in your blood (hypoxemia)
- drinking a lot due to a dry mouth (psychogenic polydipsia)
- if you have recently been operated on
- if you have certain diseases of the nervous system
- if you are taking certain antiepileptic and psychiatric medicines

Other medicines and Sodium 0.45 Infusion

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

It is particularly important that you inform your doctor if you are taking:

- corticosteroids (anti-inflammatory medicines)
- carbenoxolone (an anti-inflammatory medicine used to treat stomach ulcers)

  These medicines can cause the body to accumulate sodium and water, leading to:
  - tissue swelling due to fluid collection under the skin (oedema)
  - high blood pressure (hypertension)
- Lithium (used to treat psychiatric illness)
- Some medicines act on the hormone vasopressin. These may include:
  - anti-diabetic medication (chlorpropamide)
  - cholesterol medicine (clofibrate)
  - some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
  - selective serotonin reuptake inhibitors (used to treat depression)
  - antipsychotics
  - opioids for severe pain relief
  - medicines for pain and/or inflammation (also known as NSAIDs)
  - medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination), terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)
  - anti-epileptic medication (carbamazepine and oxcarbazepine)
  - diuretics (water tablets).

Sodium 0.45 Infusion with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding

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

If another medicine is to be added to your solution for infusion during pregnancy or breast-feeding you should:

- consult your doctor
- read the Package Leaflet of the medicine that is to be added

Driving and using machines

Ask your doctor or nurse for advice before driving or using machines.

3. How you will be given Sodium 0.45 Infusion

Sodium 0.45 Infusion will be given to you by a doctor or nurse. Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight, condition, the reason for treatment and whether or not the infusion is being used to deliver or dilute another medicine.

The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Sodium 0.45 Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Sodium 0.45 Infusion will usually be given to you through a plastic tube attached to a needle in a vein. Usually a vein in your arm is used to give you the infusion. However, your doctor may use another method to give you the medicine.

Before and during the infusion, your doctor will monitor:

- the amount of fluid in your body
- the acidity of your blood and urine
- the amount of electrolytes in your body (particularly sodium, in patients with high level of vasopressin, or are taking other medicines which increase the effect of vasopressin).

This is especially important for children as they have a limited ability to regulate fluids and electrolytes.

Any unused solution should be thrown away. You should NOT be given an infusion of Sodium 0.45 Infusion from a bag that has been partly used.

If you receive more Sodium 0.45 Infusion than you should

If you are given too much Sodium 0.45 Infusion (over-infusion), or it is given too fast, this may lead to the following symptoms:

- build up of water in the body (oedema)
- too much water in the blood (haemodilution)
- heart problems
- acidification of the blood (acidosis), leading to tiredness, confusion, lethargy and increased breathing rate

If Sodium 0.45 Infusion is given too fast when you have higher than normal levels of salts in the blood (hypertonicity), swelling of the brain (brain oedema) is possible, especially if you often have higher than normal levels of sodium in the blood (hypernatraemia).

If you develop any of these symptoms you must inform your doctor immediately. Your infusion will be stopped and you will be given treatment depending on the symptoms.

If a medicine has been added to your Sodium 0.45 Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

If you stop receiving your Sodium 0.45 Infusion

Your doctor will decide when to stop giving you this infusion.

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.

- too much fluid in the body (overhydration) which may lead to more frequent urination (polyuria)
- changes in the concentrations of the chemicals in the blood (electrolyte disturbances)
- heart failure, if you suffer from heart disease or fluid in the lungs (pulmonary oedema)
- low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorder (acute hyponatraemic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema/swelling (see also section 2 “Warnings and precautions”).

The side effects that may occur due to the administration technique include:

- fever (febrile response)
- infection at the site of infusion
- local pain or reaction (redness or swelling at the site of infusion)
- irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused
- the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
- escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring

Other side effects noted with similar products (sodium chloride containing solutions) include:

- acidification of the blood (hyperchloraemic metabolic acidosis)
- reactions with the following symptoms have been reported:
  - hives (urticaria) which may be localised to a part of the body or widespread
  - fever (pyrexia)
  - skin rash
  - chills
  - itching (pruritus)
  - decreased blood pressure
- Other infusion site reactions:
  - hives at the infusion site.

If a medicine has been added to the solution for infusion, the added medicine may also cause side effects.

These side effects will depend on the medicine that has been added. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

Reporting of side effects

If you get any side effect, talk to your doctor or nurse. This includes any possible side effect not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom:
Via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

If any side effects occur, the infusion must be stopped.

5. HOW TO STORE SODIUM 0.45 INFUSION

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

Sodium 0.45 Infusion does not require special storage conditions.

Sodium 0.45 Infusion should NOT be given to you after the expiry date which is stated on the bag after EXP. The expiry date refers to the last day of that month.

You should not be given Sodium 0.45 Infusion, if there are particles floating in the solution or if the unit is damaged in any way.

6. Contents of the pack and other INFORMATION

What Sodium 0.45 Infusion contains

The active substance is sodium chloride: 4,5 g per litre.

The only other ingredient is water for injections

What Sodium Chloride 0.45% Infusion looks like and contents of the pack

Sodium Chloride 0.45% Solution for Infusion is a clear solution, free from visible particles. It is supplied in polyolefin/polyamide plastic bags (Viaflo). Each bag is wrapped in a sealed, protective, outer plastic overpouch.

The bag size is 500 ml

The bags are supplied in cartons. Each carton contains 20 bags of 500 ml

Marketing Authorisation Holder and Manufacturers

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This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland, UK: Sodium Chloride 0.45 % Solution for Infusion
Finland: Natriumklorid Baxter Viaflo 4,5 mg/ml infuusioneste, liuos

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For information about Sodium Chloride 0.45% Infusion or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345.

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Sodium Chloride 0.45 % Solution for Infusion

The following information is intended for medical or healthcare professionals only:

Handling and Preparation

Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.
Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.
Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
Additives may be introduced before infusion or during infusion through the re-sealable medication port. When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.
Adding medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Do not mix or administer Sodium 0.45 Infusion through the same administration set with whole blood or cellular blood components.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

1. Opening

a. Remove the Viaflo container from the overpouch just before use.
b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.

a. Suspend container from eyelet support.
b. Remove plastic protector from outlet port at bottom of container:
   - grip the small wing on the neck of the port with one hand,
   - grip the large wing on the cap with the other hand and twist,
   - the cap will pop off.
c Use an aseptic method to set up the infusion.
d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible (see paragraph 5 “Incompatibilities of additive medications” below).

To add medication before administration

a. Disinfect medication port.
b. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture re-sealable medication port and inject.
c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration

a. Close clamp on the set
b. Disinfect medication port.
c. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture re-sealable medication port and inject.
d. Remove container from IV pole and/or turn to an upright position.
e. Evacuate both ports by tapping gently while the container is in an upright position.
f. Mix solution and medication thoroughly.
g. Return container to in use position, re-open the clamp and continue administration

4. In-use shelf life (Additives)

Chemical and physical stability of any additive medication at the pH of the Sodium 0.45 Infusion in the Viaflo container should be established prior to use.

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From a microbiological point of view, the diluted product must be used immediately.

If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C unless dilution has taken place in controlled and validated aseptic conditions.

5. Incompatibilities of additive medications

As with all parenteral solutions, incompatibility of the additive medications with the solution in Viaflo container must be assessed before addition.

Those additives known to be incompatible should not be used.

In the absence of compatibility studies, this solution must not be mixed with other medicinal products.

It is the responsibility of the healthcare professional to judge the incompatibility of an additive medication with the Sodium 0.45 Infusion, by checking for eventual colour change and/or eventual appearance of precipitate, insoluble complexes or crystals. The Instructions for Use of the medication to be added must be consulted.

Before adding a drug, verify it is soluble and/or stable in water at the pH of the Sodium 0.45 Infusion (pH 4.5 to 7.0).