Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sodium Chloride 0.9% w/v Intravenous Infusion BP

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 0.9% w/v Intravenous Infusion BP', but will be referred to as 'Sodium 0.9 Infusion' throughout the remainder of this leaflet.

What is in this leaflet

1. WHAT SODIUM 0.9 INFUSION IS AND WHAT IT IS USED FOR

Sodium 0.9 Infusion is a solution of sodium chloride in water. Sodium chloride is a chemical substance (often called "salt") found in the blood.

Sodium 0.9 Infusion is used to treat:

- a loss of body water (dehydration)
- a loss of sodium from the body (sodium depletion)

Situations that may cause sodium chloride and water loss include:

- when you cannot eat or drink, due to illness or after surgery
- pronounced sweating due to high fever
- extensive skin loss, as can occur in severe burns.

Sodium 0.9 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 0.9 INFUSION

Do NOT receive Sodium 0.9 Infusion if you are suffering from any of the following conditions

- higher levels of chloride in the blood than normal (hyperchloraemia)
- higher levels of sodium in the blood than normal (hypernatraemia)

If a medicine has been added to Sodium 0.9 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
- acidification of the blood (acidosis)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- high blood pressure (hypertension)
- build-up of fluid under the skin, particularly around the ankles (peripheral oedema)
- build-up of fluid in the lungs (pulmonary oedema)
- liver disease (eg cirrhosis)
- high blood pressure during pregnancy (pre-eclampsia)
- raised production of the hormone aldosterone (aldosteronism)
- any other condition associated

with sodium retention (when the body retains too much sodium), such as treatment with steroids (see also below "Other medicines and Sodium 0.9 Infusion").

- 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 0.9 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

When you are given this infusion, your doctor will take blood and urine samples to monitor:

- the amount of fluid in your body
- your vital signs
- the amount of chemicals such as sodium and potassium in your blood (your plasma electrolytes)

This is especially important for children and (premature) babies as they can retain too much sodium due to their immature kidney function.

Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). During long term treatment with Sodium 0.9 Infusion you may need to be given extra nutrition.

Other medicines and Sodium 0.9 Infusion

Tell your doctor or nurse if you are using, have recently used or might use any other medicines.

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

- corticosteroids (anti-inflammatory medicines)

These medicines can cause the body to accumulate sodium and water, leading to tissue swelling due to fluid collection under the skin (oedema) and 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 reliefmedicines 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 0.9 Infusion with food and drink

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

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 or nurse for advice before taking this medicine.

However, 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 0.9 INFUSION

Sodium 0.9 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 0.9 Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Sodium 0.9 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 levels of the hormone vasopressin, or are taking other medicines which increase the effects of vasopressin).

Any unused solution should be thrown away. You should NOT be given an infusion of Sodium 0.9 Infusion from a bag that has been partly used.

If you receive more Sodium 0.9 Infusion than you should

If you are given too much Sodium 0.9 Infusion (over-infusion), this may lead to the following symptoms:

- nausea (feeling sick)
- vomiting
- diarrhoea (loose stools)
- stomach cramps
- thirst
- dry mouth
- dry eyes
- sweating
- fever
- rapid heart rate (tachycardia)
- raised blood pressure (hypertension)
- kidney failure (renal failure)
- fluid collection in the lungs making it difficult to breathe (pulmonary oedema)
- fluid collection under the skin, particularly around the ankles (peripheral oedema)
- stopping breathing (respiratory arrest)
- headache
- dizziness
- restlessness
- irritability
- weakness
- muscular twitching and stiffness
- convulsions
- acidification of the blood (acidosis), leading to tiredness, confusion, lethargy and increased breathing rate
- higher levels of sodium in the blood than normal (hypernatraemia), which can lead to seizures, coma, swelling of the brain (cerebral edema) and death

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 0.9 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.

Stop receiving your Sodium 0.9 Infusion

Your doctor will decide when to stop giving you this infusion.
If you have any further questions on the use of this product, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The frequency of the side-effects is unknown.

- tremor
- decreased blood pressure

- hives (urticaria)
- skin rash
- itching (pruritus)

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 in the section 2 “Warning and precautions”).

Side effects that may occur due to the administration technique include:

- 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.
- an excess of fluid in the blood vessels (hypervolaemia)
- itching at the site of infusion (urticaria)
- fever (pyrexia)
- chills

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

- higher levels of sodium in the blood than normal (hypernatraemia)
- lower levels of sodium in the blood than normal (hypornatraemia)
- acidification of the blood linked with a higher level of chloride in the blood than normal (hyperchloremic metabolic acidosis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects 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.

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal
If any side effects occur, the infusion must be stopped.

5. HOW TO STORE SODIUM 0.9 INFUSION

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

50 ml and 100 ml bags: do not store above 30°C.
250 ml, 500 ml and 1000 ml bags: this medicine does not require any special storage conditions.

You should NOT be given this medicine 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 this medicine 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 0.9 Infusion contains

The active substance is sodium chloride: 9 g per litre
The only other ingredient is water for injections

What Sodium 0.9 Infusion looks like and contents of the pack

Sodium 0.9 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 sizes are:

- 50 ml
- 100 ml
- 250 ml
- 500 ml
- 1000 ml

Pack sizes:

- 50 bags of 50 ml per carton
- 75 bags of 50 ml per carton
- 1 bag of 50 ml
- 50 bags of 100 ml per carton
- 60 bags of 100 ml per carton
- 1 bag of 100 ml
- 30 bags of 250 ml per carton
- 1 bag of 250 ml
- 20 bags of 500 ml per carton
- 1 bag of 500 ml
- 10 bags of 1000 ml per carton
- 1 bag of 1000 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:
United Kingdom
Baxter Healthcare Ltd
Caxton Way, Thetford,
Norfolk, IP24 3SE
United Kingdom

Ireland and Malta
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht,
Netherlands

Manufacturers:

Baxter S.A.
Boulevard René Branquart, 80
7860 Lessines
Belgium

Baxter Healthcare Ltd.
Caxton Way,
Thetford Norfolk IP24 3SE
United Kingdom

Bieffe Medital S.A.
Ctra de Biescas, Senegüé
22666 Sabiñanigo (Huesca)
Spain

Baxter Healthcare S.A.
Moneen Road
Castlebar
County Mayo
Ireland

Bieffe Medital S.P.A.
Via Nuova Provinciale
23034 Grosotto (SO)
Italy

This leaflet was last revised in March 2019

For information about Sodium Chloride 0.9% 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.

Baxter

Sodium Chloride 0.9% w/v Intravenous Infusion BP

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.

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 gauge (1.10 mm) to 22 gauge (0.70 mm) 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 gauge (1.10 mm) to 22 gauge (0.70 mm) 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 0.9 Infusion in the Viaflo container should be established prior to use. From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

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.
In the absence of compatibility studies, this solution must not be mixed with other medicinal products.
It is the responsibility of the physician to judge the incompatibility of an additive medication with the Sodium 0.9 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 0.9 Infusion.
Those additives known to be incompatible should not be used.