Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sodium Chloride Intravenous Infusion BP 0.9% w/v

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 Intravenous Infusion BP 0.9% w/v, 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

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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 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 0.9 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 if you 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)

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

Low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorders (acute hyponatraemic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema/swelling (see also section 2 “Warnings and precautions”).

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 (hyponatraemia)
- 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:
http://www.mhra.gov.uk/yellowcard

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.

VIAFLEX containers should be stored within their overpouch at a temperature below 25°C.

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 other ingredients are:

- hydrochloric acid
- water for injections
- sodium hydroxide.

What Sodium Chloride 0.9 Infusion looks like and contents of the pack

Sodium chloride 0.9 Infusion is a clear solution, free from visible particles. It is supplied in a plastic VIAFLEX infusion bag made from PVC.

The solution is supplied in a plastic Viaflex container fabricated from PVC. The bag is sized to contain either 50ml, 100ml, 150ml, 250ml, 500ml or 1000ml and is sealed in a plastic overpouch.

The 250ml containers may also incorporate a pre-attached polycarbonate reconstitution device (also referred to as MiniBag Plus).

The 50 and 100ml containers incorporate a pre attached polycarbonate reconstitution device (also referred to as MiniBag Plus).

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

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

Send all enquiries to this address.

Sodium chloride 0.9 Infusion can be made at any of these addresses:

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

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

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

This leaflet was last revised in March 2020

For information about Sodium Chloride 0.9%w/v Solution for 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 Intravenous Infusion BP 0.9% w/v

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

Handling and Preparation

The solution for infusion should be visually inspected prior to use.

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.

Preparation for Administration
VIAFLEX

The VIAFLEX container has an outlet port designed for an administration set with a short single connector. If an administration set with a combined air inlet/fluid path connector has to be used, ensure the air inlet tube is always clamped off.

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1. Opening

a. Remove the protective overpouch by tearing down from notch and remove container.

b. Carefully straighten hanger and ports, if necessary.

c. Squeeze container and inspect for minute leaks and examine solution for visible particles or cloudiness by viewing along seam.

d. Discard unit if leaks, particles or cloudiness are evident.

2. Preparation for administration

Use sterile material for preparation and administration.

a. Suspend container from base eyelet support.

b. Use an aseptic technique to prepare the administration set.

c. Remove blue protector from outlet port and insert set connector well into port.

d. Prime set and regulate administration as required.

e. If administration set becomes blocked do not pump contents back into container but replace equipment.

f. Discard any unused portion and equipment after use. Do not store or reconnect partly used containers.

3. Techniques for injection of additive medications

The VIAFLEX container has a second port with a self-sealing rubber medication port designed for the addition of medication using a syringe. This is the only port for adding medication.
Warning: Additives may be incompatible.

To add medication before administration

a. Swab the medication port with the appropriate anti-bacterial fluid in line with current recommended practice and procedure.

b. Using a syringe with a 20 – 22 gauge needle, puncture re-sealable medication port and inject. Do not leave the syringe and needle in the port once the medication has been injected.

c. Shake and squeeze the VIAFLEX container so that the solution and medication are thoroughly mixed. For high density medications such as potassium chloride, squeeze both ports while upright and invert the container several times while shaking and squeezing to ensure thorough mixing.

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 a syringe with a 20 – 22 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.

Cautions

a. Do not vent.

b. Do not administer unless the solution is clear and container undamaged.

c. Do not use in series connections as this could result in air embolism due to residual air being drawn from the primary container before administration of fluid from the secondary container is completed.

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d. Discontinue infusion if adverse reaction occurs.

e. Rapid infusion may be harmful.

f. It is recommended that the intravenous administration set be replaced at least once every 24 hours. Details of the use of the set can be recorded – record labels are available from Baxter Healthcare Ltd.

4. In-use shelf life

Chemical and physical stability of any additive medication at the pH of the Sodium chloride 0.9 Infusion in the VIAFLEX container should be established prior to use.

From a microbiological point of view, the diluted product should 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 reconstitution has taken place in controlled and validated aseptic conditions.

5. Incompatibilities of additive medications

WARNING: Additives may be incompatible. The introduction of additives to any solution, regardless of type of container, requires special attention to assure that no incompatibilities result.

While some incompatibilities are readily observed, it is important to be aware that subtle physical, chemical and pharmacological incompatibilities can occur. The medical literature, the additive package insert and other available sources of information should be reviewed for a more thorough understanding of possible incompatibility problems.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives into this solution, aseptic technique must be employed.

It is recommended that medication is added only under Pharmaceutical supervision.

Do not add medication before hanger and ports have been straightened and the container inspected.

Do not store solutions with added medication. Before adding a drug, verify it is soluble and stable in water at the pH of the Sodium chloride 0.9 Infusion.

Those additives known to be incompatible should not be used.

Preparation for Administration

MINIBAG PLUS

The Minibag Plus Container is a standard diluent container with an integral closed system transfer device (CSTD) drug vial adaptor. It allows for drug admixture after connection to a single dose powder or liquid (up to 10 mL) drug vial having a 20 mm closure. A breakaway seal in the tube between the vial adaptor and the container is broken to allow transfer of the diluent into the vial and reconstitution of the drug.

During the vial docking process, vapor and drug powder in the vial are contained within the container/vial system.

Once the vial has been docked to the vial adaptor, the Minibag Plus is designed to prevent ingress of micro-organisms and limit escape of drug powder and vapour from the reconstituted drugs, minimising environmental and user exposure

The reconstituted drug is then transferred from the vial into the container diluent and mixed to result in an admixture for delivery to the patient.

Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier. The inner bag maintains the sterility of the product.

1. To open, tear overwrap down side at slit and remove solution container. Straighten hanger and ports and inspect for minute leaks by squeezing inner bag firmly. Check to ensure seals are intact and blue frangible is not leaking. If leaks are found discard unit as sterility or function may be impaired.
2. Remove protective cover of drug vial and swab with appropriate disinfectant.
3. Observing aseptic technique, peel back the foil cover from end of reconstitution device. Fig. 1.
4. Place the drug vial on a flat surface. Hold the reconstitution device with your thumb and index finger and push the device over the drug vial, puncturing the stopper and locking in place. Fig. 2.
5. Just prior to administration, break blue frangible connector. Grip top of blue frangible connector between thumb and forefinger of one hand. Grip base of frangible with thumb and forefinger of other hand. Break frangible seal by bending 90° in one direction then 180° in the opposite direction. Fig. 3.
6. For liquid drug vials proceed directly to Step 8. For powder drug vials position the drug vial below the Minibag Plus and squeeze the Minibag Plus to transfer solution thereby partially filling the vial approximately 1/2 full. Fig. 4.
7. Keep the reconstitution device attached to the drug vial. Agitate the vial gently to dissolve the drug in the vial
8. Invert the drug vial above the Minibag Plus. Squeeze the Minibag Plus to force air into the vial, then release the pressure on the Minibag Plus by relaxing your hand and allowing the reconstituted drug to flow back into the Minibag Plus container. Repeat procedure until vial is empty of all drug. Fig. 5.
9. Immediately prior to administration, examine solution for any visible particles.
10. Label the Minibag Plus according to hospital procedures. Fig. 6.
11. Do not detach drug vial from reconstitution device at any time

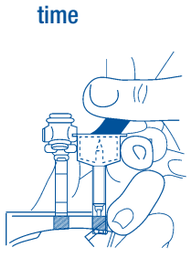

Fig. 1

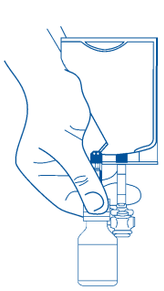

Fig. 2

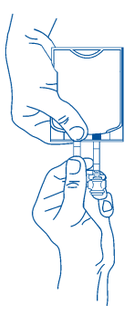

Fig. 3

Fig. 4

Fig. 5

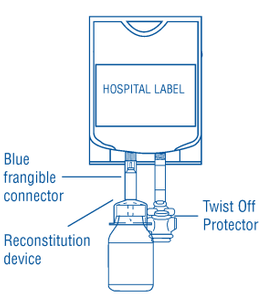

Fig. 6

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Preparation for Administration

Minibag Plus containers have an outlet port designed for an administration set with a single connector. If an administration set with a combined air inlet/fluid path connector has to be used, ensure the air inlet tube is always clamped off.

1. Suspend container from D-shaped hanger.
2. Using aseptic technique prepare administration set.
3. Remove the protector from the administration port as follows:
   a. with one hand, grip the wings of the blue protector below the fracture zone (a)
   b. with the other hand, grip the wings above the fracture zone (b)
   c. remove the upper section of the protector with one twisting movement (c)
   d. insert the set connector well into the port (d)
4. Prime set and regulate administration as required. If administration set becomes blocked do not pump contents back into container but replace equipment.
5. Discard any unused portion and equipment after use. Do not store or reconnect partly used containers.