Package leaflet: Information for the user

Sodium Chloride 0.3% w/v & Glucose 3.3% w/v Solution for Infusion BP

Active substances: sodium chloride, glucose.

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 0.3% w/v & Glucose 3.3% w/v Solution for Infusion BP', but will be referred to as 'Sodium Chloride 0.3 & Glucose 3.3 Infusion' throughout the remainder of this leaflet.

What is in this leaflet

1. What Sodium Chloride 0.3 & Glucose 3.3 Infusion is and what it is used for

Sodium Chloride 0.3 & Glucose 3.3 Infusion is a solution of the following substances in water:
- sugar (glucose)
- sodium chloride (salt)

Glucose is one of the body's sources of energy. This solution for infusion provides 132 kilocalories per litre. Sodium and chloride are chemical substances found in the blood.

Sodium Chloride 0.3 & Glucose 3.3 Infusion is used:
- as a source of carbohydrate (sugar)
- to treat a loss of body water (dehydration) and chemicals (e.g. by heavy sweating, kidney disorders)
- to treat you, if the volume of blood in your blood vessels is low (hypovolaemia)

2. What you need to know before you are given Sodium Chloride 0.3 & Glucose 3.3 Infusion

Do NOT receive Sodium Chloride 0.3 & Glucose 3.3 Infusion if you are suffering from any of the following conditions
- when you know you are allergic to the product
- when there is too much fluid in the spaces around the cells of the body (extracellular hyperhydration)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- more fluid and sodium than normal in the body (fluid and sodium retention)
- severe kidney problems that mean you produce less urine than usual or none at all (oliguria or anuria)
- uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as:
    - shortness of breath
    - swelling of the ankles
- lower levels of sodium in the blood than normal (hyponatraemia)
- lower levels of chloride in the blood than normal (hypochloraemia)
- 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)
- diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (uncompensated diabetes)
- other states of glucose intolerance, for example:
    - metabolic stress (when the body's metabolism does not function correctly, e.g. due to severe illness)
    - hyperosmolar coma (unconsciousness). This is a type of coma that can occur if you have diabetes and do not receive enough medicine.
    - a very high amount of sugar in the blood (significant hyperglycaemia)
    - higher levels of lactate in the blood than normal (hyperlactataemia)

Warnings and precautions
Please tell your doctor if you have or have had any of the following medical conditions:
- conditions associated with sodium retention, fluid overload and oedema, such as:
  -aldosteronism (a disease that causes high levels of a hormone called aldosterone) associated with:
    - high blood pressure (hypertension)
    - heart failure
    - poor liver function or liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
    - poor kidney function
  - high blood pressure during pregnancy (pre-eclampsia)
- taking certain medications, see below: "Other medicines and Sodium Chloride 0.3 & Glucose 3.3 Infusion")
- a disorder in which the blood becomes too alkaline (metabolic alkalosis)
- muscle weakness and periodic paralysis due to low thyroid activity (thyrotoxic periodic paralysis)
- rapid loss of water from the body e.g. due to vomiting or diarrhoea
- being on a low potassium diet for a long time
- allergy, in particular to corn (Sodium Chloride 0.3 & Glucose 3.3 Infusion contains sugar derived from corn)
- 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 Chloride 0.3 & Glucose 3.3 Infusion").

  This may increase the risk of low level 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)
    - anyone with a condition such as low levels of oxygen in your blood (hypoxemia),
    - people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury

The infusion may cause:
- changes in the concentrations of the chemicals in the blood (electrolyte disturbances)
- a build up of fluid under the skin, affecting all parts of the body (general oedema), around the ankles (peripheral oedema) or in the lungs (pulmonary oedema)

When you are given this infusion, your doctor will take blood and urine samples to monitor:
- the amount of chemicals such as sodium and chloride in your blood (your plasma electrolytes)
- the amount of sugar (glucose)

As Sodium Chloride 0.3 & Glucose 3.3 Infusion contains sugar (glucose), it can cause a high level of sugar in the blood (hyperglycaemia). If this occurs, your doctor may:
- adjust the speed of infusion
- give you insulin to reduce the blood sugar levels

This is particularly important:
- if you are diabetic
- if you have not been eating well or have been drinking too much alcohol for a long time
- if you have recently had a stroke (acute ischaemic stroke). High levels of sugar in the blood can worsen the effects of stoke and affect recovery
- if you have had head injury within the past 24 hours

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 Chloride 0.3 & Glucose 3.3 Infusion, you may need to be given extra nutrition. Your doctor should also monitor the level of potassium in your blood to avoid this becoming lower than normal (hypokalaemia).

Children
Special care should be taken when giving this solution to children, infants, and newborns (especially premature babies and those with low birth weight). Children, infants and newborns may not have a good ability to handle the chemicals in the solution.

Younger children are at an increased risk of developing levels of sugar in the blood that are either too high or too low, and therefore need close monitoring during treatment to ensure that sugar levels are controlled. Low sugar levels in newborns can cause prolonged seizures, coma and brain damage. High sugar levels have been associated with bleeding into the brain, bacterial and fungal infection, damage to the eye (retinopathy of prematurity), infections in the intestinal tract, lung problems, prolonged length of hospital stay and death.

Children are at higher risk for having or developing a too low sodium concentration in their blood (hyponatraemia). Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death. Acute hyponatraemic encephalopathy is a serious complication, especially in children.

Your doctor knows this and will closely monitor the amount of chemicals such as glucose (sugar), sodium and chloride in your child's blood (plasma electrolytes).

Other medicines and Sodium Chloride 0.3 & Glucose 3.3 Infusion
Tell your doctor or nurse if you are taking or have recently taken 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) or high blood pressure (hypertension).

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 or opioids for severe pain relief
- medicines for pain and/or inflammation (also known as NSAIDs)
- medicines that imitate or strengthen the effects of vassopressin 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).

Other medicines that can affect or be affected by Sodium Chloride 0.3 & Glucose 3.3 Infusion:
- lithium (used to treat psychiatric illnesses)
- insulin (used to treat diabetes)
- beta blockers (heart tablets)

Sodium Chloride 0.3 & Glucose 3.3 . Infusion with food and drink and alcohol
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.
Sodium Chloride 0.3 & Glucose 3.3 Infusion can be used during breastfeeding.
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
Sodium Chloride 0.3 & Glucose 3.3 Infusion does not affect your ability to drive or use machines.

3. How you will be given Sodium Chloride 0.3 & Glucose 3.3 Infusion

You will be given Sodium Chloride 0.3 & Glucose 3.3 Infusion 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 and the reason for treatment. The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Sodium Chloride 0.3 & Glucose 3.3 Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Sodium Chloride 0.3 & Glucose 3.3 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 Chloride 0.3 & Glucose 3.3 Infusion from a bag that has been partly used.

If you receive more Sodium Chloride 0.3 & Glucose 3.3 Infusion than you should
If you are given too much Sodium Chloride 0.3 & Glucose 3.3 Infusion (over-infusion) or if it is given too fast, this may lead to the following symptoms:

- high levels of sugar in the blood (hyperglycemia) Symptoms include:
  - dry mouth due to lack of water in body tissues (dehydration)
  - thirst
  - frequent urination due to increased urine production (osmotic diuresis)
  - blurred vision
  - fatigue
- low levels of sodium in the blood (hyponatraemia). Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death
- build-up of fluid in the body causing swelling (oedema)

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 Chloride 0.3 & Glucose 3.3 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 Chloride 0.3 & Glucose 3.3 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.

The side effects can be related to Sodium Chloride 0.3 & Glucose 3.3 Infusion itself. This includes:
- hypersensitivity reactions, including a serious allergic reaction called anaphylaxis (potential manifestation in patients with allergy to corn)
- high level of sugar in the blood (hyperglycaemia)
- low levels of sodium in the blood that may be acquired during hospitalization (nosocomial hyponatraemia) and related neurological disorders (acute hyponatremic encephalopathy). Hyponatraemia can lead to irreversible brain injury and death due to cerebral oedema/swelling (see also in section 2 "warning and precautions")

The side effects can be related to the administration technique. This includes:
- fever (febrile response)
- chills
- itching (pruritus) or rash
- local pain or reaction (pain or vesicles at the site of infusion)
- irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain , swelling or vesicles along the path of the vein into which the solution is infused.

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 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.

5. How to store Sodium Chloride 0.3 & Glucose 3.3 Infusion

Keep this medicine out of the sight and reach of children.
Sodium Chloride 0.3 & Glucose 3.3 Infusion does not require special storage conditions.

Sodium Chloride 0.3 & Glucose 3.3 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 Chloride 0.3 & Glucose 3.3 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 Chloride 0.3 & Glucose 3.3 Infusion contains
The active substances are:
- sugar (glucose): 33 g per litre
- sodium chloride: 3 g per litre

The only other ingredient is water for injections.

What Sodium Chloride 0.3 & Glucose 3.3 Infusion looks like and contents of the pack

Sodium Chloride 0.3 & Glucose 3.3 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:
- 250 ml
- 500 ml
- 1000 ml.

The bags are supplied in cartons. Each carton contains one of the following quantities:
- 30 bags of 250 ml
- 20 bags of 500 ml
- 10 bags of 1000 ml.
- 12 bags 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 SA
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 Manufacturing Sp. z.o.o.
42 B Wojciechowska Str.
20-704 Lublin
Poland

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For information about Sodium Chloride 0.3 & Glucose 3.3 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.

The following information is intended for 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. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

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 tonicity prior to parenteral administration.

- From a physico-chemical viewpoint, solution containing additives should be used immediately unless chemical and physical in-use stability has been established.
- From a microbiological point of view, solutions containing additives should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2 to 8°C, unless addition has taken place in controlled and validated aseptic conditions.

Discard after single use.
Discard any unused portion.

Do not reconnect partially used bags.

1. <u>Opening</u>

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. <u>Preparation for administration</u>

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. <u>Techniques for injection of additive medicinal products</u>

Warning: Additives may be incompatible (see Paragraph 5 "Incompatibilities of additive medicinal products" below).

To add medicinal products 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 medicinal product thoroughly. For high-density medicinal products such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: for storage of bags containing additives, refer to In-use shelf-life instructions in section 4.

To add medicinal products 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 medicinal product thoroughly.
g. Return container to in use position, re-open the clamp and continue administration.

4. <u>In-use shelf-life:</u> Additives

The chemical and physical stability of any additive at the pH of Sodium Chloride 0.3 & Glucose 3.3 Infusion in the Viaflo container should be established prior to use.
From a physico-chemical viewpoint, solution containing additives should be used immediately unless chemical and physical in-use stability has been established.
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. <u>Incompatibilities of additive medicinal products</u>

As with all parenteral solutions, before adding medicinal products, compatibility of these additives with the solution in Viaflo container must be assessed.

It is the responsibility of the physician to judge the incompatibility of an additive medicinal product with the Sodium Chloride 0.3 & Glucose 3.3 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 stable in water at the pH of Sodium Chloride 0.3 & Glucose 3.3 Infusion (pH 3.5 – 6.5).

When a compatible medicinal product is added to the Sodium Chloride 0.3 & Glucose 3.3 Infusion, the solution must be administered immediately, unless chemical and physical in-use stability has been established.

As guidance the following medicinal products are incompatible with the Sodium Chloride 0.3 & Glucose 3.3 Infusion (***non-exhaustive listing***):

- Ampicillin sodium
- Mitomycin
- Erythromycin lactobionate
- Human insulin

Because of the presence of glucose, Sodium Chloride 0.3 & Glucose 3.3 Infusion should not be administered through the same infusion equipment as whole blood, as haemolysis and clumping can occur.

Those additives known to be incompatible should not be used.