Package leaflet: Information for the user

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

Read all of this leaflet carefully before 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion is and what it is used for

This medicine is a solution of sodium chloride administered to you through a tube placed into a vein (intravenous drip).
It contains sodium chloride at a concentration similar to the concentration of salts in your blood.

You will receive it for fluid and salt supplies when:
- you have a lack of body fluids (isotonic dehydration)
- you have a lack of body fluids and your blood sodium level is abnormally low (hypotonic dehydration)
- you have a low blood chloride level and abnormally high blood pH (hypochloraemic alkalosis)
- you have lost sodium or chloride

This solution is also used:
- for immediate replenishment of your blood volume after you have lost blood,
- as a vehicle to deliver other electrolytes or medicinal products,
- for treatment of wounds and moistening of wound tamponades and dressings.

2. What you need to know before you use Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion

Do not use Sodium Chloride Intravenous Infusion BP 0.9% w/v

- if you have too much water in your body (hyperhydration).

- if you have been told that you have a severe increase of sodium or chloride in your blood (severe hypernatraemia or severe hyperchloraemia).

Warnings and precautions

Talk to your doctor or pharmacist before taking Sodium Chloride Intravenous Infusion BP 0.9% w/v

if you have:
- abnormally low level of potassium in the blood (hypokalaemia)
- abnormally high level of sodium in the blood (hypernatraemia)
- abnormally high level of chloride in your blood (hyperchloraemia)
- any disease where your sodium intake must be low, such as heart disease (cardiac insufficiency), severe kidney disease (severe renal insufficiency), swelling of the body tissues due to excess water in your body tissues (generalised oedema),water in your lungs (pulmonary oedema), high blood pressure (hypertension), or eclampsia, a disease occurring during pregnancy, with high blood pressure, cramps, and swelling (oedema)

While you are receiving this medicinal product, your serum electrolyte levels, water balance, and the acid-base status will be checked from time to time.

Your heart and lung function will be monitored, if a rapid infusion of the solution is necessary.

In order to avoid brain damage (osmotic demyelination syndrome) your doctor will make sure that your blood sodium level will not increase too fast.

If the solution is used as a vehicle to deliver other electrolytes or medicinal products, your doctor will consider the safety information of the medicine to be dissolved or diluted in Sodium Chloride Intravenous Infusion BP 0.9% w/v.

Children

Premature or term infants may retain an excess of sodium due to insufficient renal function. Therefore, repeated infusions of sodium chloride will only be given by the doctor after determination of the serum sodium level.

Other medicines and Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion

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

Your doctor will take special care about you if you receive/take medicines that make you retain sodium (e.g. corticosteroids or non-steroidal anti-inflammatory drugs) as these may cause fluid accumulation in body tissue (oedema).

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 for advice before taking this medicine.

Pregnancy
Sodium Chloride Intravenous Infusion BP 0.9% w/v can be used as indicated.

Special care will be taken if you have a specific disorder that may occur during pregnancy, called eclampsia, with the following symptoms: high blood pressure, cramps, swelling.

Breast-feeding
As the concentration of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated. Sodium Chloride Intravenous Infusion BP 0.9% w/v can be used during breast-feeding, if required.

Driving and using machines
Sodium Chloride Intravenous Infusion BP 0.9% w/v does not influence your ability to drive and use machines.

3. How to use Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution or Infusion

The medicinal product is for intravenous use or is used for rinsing or moistening.

Dosage
Adults
The amount of the medicinal product that you will be given depends on your needs of water and salts (electrolytes).

Maximum dose
Up to 40 ml per kg body weight per day will be given to you. This means that you will receive up to 6 mmol of sodium per kg body weight per day.
In case of e.g. fever, diarrhoea or vomiting your doctor will replace the additional loss depending on the volume and composition of the lost fluid.

The administration rate will depend on your needs of water and salts (electrolytes).

Elderly individuals will be carefully monitored. In elderly patients, it may be necessary to adjust the dosage stated to avoid circulatory and kidney problems due to hydration.

Exceptionally, if you urgently require replacement of lost blood volume, you may receive this solution rapidly by pressure infusion. Then utmost care will be taken to expel all air from the container and tubing before the infusion is started to avoid the risk of air embolism.

The amount used for rinsing and moistening depends on actual requirements.

Use in Children
Your doctor will determine the dosage for your child individually.

If you use more Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion than you should:
An overdose could lead to abnormally high fluid, sodium and chloride levels in your blood, tissue fluid accumulation (oedema) and/ or high levels of acidic substances in your blood (your blood getting sour).
First sign of overdose can be thirst, confusion, sweating, headache, weakness, somnolence or tachycardia.
If your sodium level increases too rapidly your brain may become damaged (osmotic demyelination syndrome).

In such a case your infusion will be stopped immediately. Additionally you may be given water tablets to increase your urine flow. Your blood electrolyte levels will be monitored continuously.

Your doctor will decide on further medication or other measures to normalise your electrolyte levels, water balance and acid-base balance.

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

4. Possible side effects

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

If this medicine is used according to the directions given, no side effects are expected.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion

This medicinal product does not require any special storage conditions.

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 labels on the bottle or the bag and on the outer carton. The expiry date refers to the last day of that month.

Do not use the medicinal product if you notice that the solution appears cloudy or coloured, if you find particles in the solution or if the container is leaking. The containers are for single use only. After use container and any remaining contents have to be discarded.

After dilution or admixture of additives :
From a microbiological point of view, the 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.

6. Contents of the pack and other information

What Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion contains

– The active substance is Sodium Chloride
Each 1000 ml of the solution contains 9.0 g of sodium chloride

– The other ingredient is water for injections

What Sodium Chloride Intravenous Infusion BP 0.9% w/v Solution for Infusion looks like and contents of the pack

Sodium Chloride Intravenous Infusion BP 0.9% w/v is a clear colourless solution of sodium chloride in water.

It comes in:

- Polyethylene bottles, contents: 250 ml, 500 ml, 1000 ml
  available in packs of 10 × 250 ml
  10 × 500 ml
  10 × 1000 ml

Marketing Authorisation Holder

PA Holder:
B. Braun Medical Ltd.
3 Naas Road Industrial Park, Dublin 12, Ireland

Manufacturers:

B. Braun Melsungen AG Carl-Braun-Straße 1 34212 Melsungen Germany	or	B. Braun Medical S. A. Carretera de Terrassa 121 08191 Rubí (Barcelona) Spain

This leaflet was last revised in July 2018.

The following information is intended for healthcare professionals only:

To prevent development of the osmotic demyelination syndrome the increase of the serum sodium level should not exceed 9 mmol/l/day. As a general recommendation a correction rate of 4 to 6 mmol/l/day is reasonable in most cases, depending on patient condition and concomitant risk factors.