Package Leaflet: Information for the patient

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Sodium Chloride Injection BP 0.9% w/v

Read all of this leaflet carefully before you start 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 your pharmacist.
- 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 Injection BP 0.9% w/v is and what it is used for

Sodium (common salt) occurs naturally in your body. A solution of 0.9% sodium chloride in water for injections is the same strength as your blood. It is used to:
- prime giving sets before blood or other medicines are given to you.
- replace the loss of sodium from your body.
- deliver or dilute other medicines that may be given to you (because it occurs naturally in the body).
- irrigate (wash) surfaces of your body.

2. What you need to know before you are given Sodium Chloride Injection BP 0.9% w/v

You should NOT be given Sodium Chloride Injection BP 0.9% w/v if you:
- have higher levels of chloride in the blood than normal (hyperchloraemia)
- have higher levels of sodium in the blood than normal (hypernatraemia)

If a medicine has been added to Sodium Chloride Injection BP 0.9%, the Package Leaflet of the added medicine must be consulted to determine whether or not you can receive the solution.

Warnings and precautions

Talk to your doctor or nurse before being given the injection if you have had any of the following medical conditions:
- heart disease or heart failure
- impaired kidney function
- acidification of the blood (acidosis)
- liver disease (e.g. cirrhosis)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- high blood pressure (hypertension)
- pre-eclampsia (high blood pressure during pregnancy)
- fluid retention resulting in swelling of parts of the body, particularly your feet and ankles (peripheral oedema) or build-up of fluid in the lungs (pulmonary oedema).
- 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 Chloride Injection BP 0.9% w/v ”)
- raised production of the hormone aldosterone (aldosteronism)
- 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 Injection BP 0.9% w/v ”)

  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

Other medicines and Sodium Chloride Injection BP 0.9% w/v

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). 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).

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 pharmacist for advice before receiving this medicine. If another medicine is to be added to your solution for infusion during pregnancy or breast-feeding you should consult your doctor and read the Package Leaflet of the medicine that is to be added.

Driving and using machines

You should not drive or use machinery if you are affected by the administration of Sodium Chloride Injection BP 0.9% w/v.

3. How you will be given Sodium Chloride Injection BP 0.9% w/v

Your nurse or doctor will give you the injection.

Your doctor will decide the correct dosage for you and how and when the injection will be given.

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.

If you receive more Sodium Chloride Injection BP 0.9% w/v than you should

If you are given too much Sodium Chloride Injection BP 0.9% w/v, this may lead to the following symptoms:
- nausea (feeling sick), vomiting
- diarrhoea (loose stools)
- stomach cramps
- thirst, dry mouth
- sweating, fever
- raised blood pressure (hypertension), decreased blood pressure (hypotension)
- rapid heart rate (tachycardia)
- kidney failure (renal failure)
- fluid collection in the lungs making it difficult to breathe (pulmonary oedema), or under the skin particularly around the ankles (peripheral oedema)
- stopping breathing (respiratory arrest)
- headache, dizziness
- restlessness, irritability
- weakness
- muscular twitching and stiffness
- convulsions
- higher levels of sodium in the blood than normal (hypernatraemia), which can lead to seizures, coma, swelling of the brain (cerebral oedema) and death

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

4. Possible side effects

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

Possible side effects are listed below:

Not known: frequency cannot be estimated from the available data

- tremor
- decreased blood pressure
- local pain or reaction (redness or swelling at the site of infusion)
- infection at the site of infusion
- itching (pruritus) at the site of infusion
- hives (urticaria), skin rash
- 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)
- fever
- chills
- 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”).

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, pharmacist or nurse: This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sodium Chloride Injection BP 0.9% w/v

Your injection will be stored at less than 25°C. The nurse or doctor will check that the injection is not past its expiry date before giving you the injection. Keep this medicine out of the sight and reach of children.

6. Contents of the pack and other information

What Sodium Chloride Injection BP 0.9% w/v contains

The active ingredient is sodium chloride (common salt) in a sterile solution. Each 1 ml of solution contains 9 mg of sodium chloride.

The other ingredients are sodium hydroxide, hydrochloric acid and water for injections.

What Sodium Chloride Injection BP 0.9% w/v looks like and contents of the pack

Sodium Chloride Injection BP 0.9% w/v is supplied in:

Clear glass ampoules, 2 ml, 5 ml, 10 ml and 20 ml. Packed in cardboard cartons to contain 10 ampoules.

Clear glass vials (33 ml, 100 ml and 200 ml) with bromobutyl rubber stopper, plastic outer cap and inner aluminium ring.

Clear glass vials 50 ml with chlorbutyl rubber stopper, plastic outer cap and inner aluminium ring.

Not all pack sizes may be marketed.

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