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Prescriber Information Leaflet

B. Braun Pharmaceuticals EPZ Ltd.

Sodium Chloride Intravenous Infusion BP 0.9% w/v NaCl 0.9%

Please read this leaflet carefully before you start to administer Sodium Chloride Intravenous Infusion BP 0.9% w/v

What is in the bottle?
Sodium Chloride Intravenous Infusion BP 0.9% w/v v is a solution of Sodium Chloride in Water for Injection. The active substance is Sodium Chloride 9g per litre.

What Sodium Chloride Intravenous Infusion BP 0.9% w/v looks like and contents of the pack
Sodium Chloride Intravenous Infusion BP 0.9% w/v is a clear solution, free from visible particles. It is supplied in plastic containers of 500ml.

What is Sodium Chloride Intravenous Infusion BP 0.9% w/v used for?
Sodium Chloride Intravenous Infusion BP 0.9% w/v is used as a source of fluid and to dilute or deliver other medicines that can be given by infusion.

Before You Administer Sodium Chloride Intravenous Infusion BP 0.9% w/v
DO NOT administer Sodium Chloride Intravenous Infusion BP 0.9% w/v if the patient is suffering from any of the following conditions:
- Severe Renal impairment
- Risk of fluid / solute overload and electrolyte disturbances
- Hypernatraemia
- Hyperchloraemia
- Metabolic acidosis
- Hypervolemia

If another medicine is to be added to the solution for infusion always read the patient information leaflet of that medicine. This way you can check to see if that medicine is safe to be administered with the infusion to the patient.

Warnings and Precautions
Do not use if the container is found leaking upon squeezing, if the solution is not clear or if the solution contains particulate matter.
Please verify if the patient has had any of the following medical conditions:
- Congestive Heart failure
- Renal Disease
- Hypertension
- Primary Hyperaldosteronism

When this infusion is administered, the patient's blood samples must be taken to monitor:
- Electrolyte concentrations in their blood (plasma electrolytes)

As Sodium Chloride Intravenous Infusion BP 0.9% w/v contains Sodium chloride, it can cause a high level of sodium in the blood (hypernatraemia). If this occurs, you may:
- Adjust the speed of infusion
- Monitor electrolytes in blood

This is particularly important:
- If the patient suffers from hyperchloraemia

In disorders where restriction of Sodium intake is required, such as cardiac insufficiency, generalized oedema, hypertension, eclampsia, and severe renal insufficiency.

Use in Pregnancy and Breast-feeding
There are no adequate data from the use of Sodium Chloride 0.9% in pregnant or lactating women. The physician should carefully consider the potential risks and benefits for each specific patient before administering Sodium Chloride Intravenous Infusion BP 0.9% w/v.

Caution is advised in patients with pre-eclampsia.
- If another medicine is to be added to the solution for infusion during pregnancy or breast-feeding, read the patient information leaflet of the medicine that is to be added.

Use in Children
There is no specific paediatric dose; the dose is dependent on weight, clinical condition and laboratory results.

Plasma electrolyte concentrations should be closely monitored in the paediatric population as this population may have impaired ability to regulate fluids and electrolytes.

Other Medicines and Sodium Chloride Intravenous Infusion BP 0.9% w/v

Sodium Chloride Intravenous Infusion BP 0.9% w/v and other medicines taken at the same time can affect each other.

Caution must be exercised in the administration of Sodium Chloride Intravenous Infusion BP 0.9% w/v to patients receiving corticosteroids or corticotrophins as these are associated with the retention of sodium and water.

How to Administer Sodium Chloride Intravenous Infusion BP 0.9% w/v

Sodium Chloride Intravenous Infusion BP 0.9% w/v is administered by a doctor or a nurse. The doctor will decide on how much to administer and when it is to be given. This will depend on the patient's age, weight, condition, the reason for treatment, blood levels and whether or not the infusion is being used to deliver or dilute another medicine.

Sodium Chloride Intravenous Infusion BP 0.9% w/v will usually be administered through a plastic tube attached to a needle in a vein.

In the average adult, daily requirements of sodium and chloride are met by infusion of one litre of 0.9% w/v Sodium Chloride (150 mEq each of Sodium and Chloride) with an infusion rate of up to 40ml/kg body weight/hour.

In the management of shock higher volumes and higher rates of infusion may be administered. In patients with chronic hypernatremia the rate of infusion should be slow so that the resulting increase of the serum sodium level is limited to a maximum of 0.35mmol/l/h.

The amount administered may also be affected by other treatments the patient is receiving.

Sodium Chloride Intravenous Infusion BP 0.9% w/v should NOT be administered after the expiry date, which is stated on the container label. The expiry date refers to the last day of the month.

Sodium Chloride Intravenous Infusion BP 0.9% w/v must not be administered if there are particles floating in the solution or if the pack is damaged in any way.

Any unused solution should be thrown away. Sodium Chloride Intravenous Infusion BP 0.9% w/v must NOT be administered from a bottle that has been partly used.

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What to do if more Sodium Chloride Intravenous Infusion BP 0.9% w/v is administered than should be
If Sodium Chloride Intravenous Infusion BP 0.9% w/v is administered in a larger quantity (over-infusion) or administered too fast, this may lead to the following symptoms:
- Hypernatraemia)
- Hyperchloraemia
- Hyperhydration
- Hyperosmolarity of the serum
- Metabolic acidosis

If any of the above symptoms are developed by the patient, stop the infusion immediately and treat the symptoms.
Administer diuretics with continuous monitoring of serum electrolytes and correction of acid-base imbalances.

If a medicine has been added to the Sodium Chloride Intravenous Infusion BP 0.9% w/v before over-infusion occurs, that medicine may also cause symptoms. Ensure you read the patient information leaflet of the added medicine for a list of possible symptoms.

When to stop Administering Sodium Chloride Intravenous Infusion BP 0.9% w/v
The doctor will decide when to stop administering this infusion.

Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects can include:
- Metabolic acidosis
- Tremor
- Rash, pruritus
- Hypernatraemia leading to osmotically induced water shift, decreasing intracellular volume i.e. dehydration or internal organs especially the brain causing thrombosis and haemorrhage
  - 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 burning 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 and pain in the area of the clot.
  - Escape of the infusion solution into the tissue around the vein (extravasation). This can damage the tissue and cause scarring.

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. Please read the patient information leaflet of the added medicine for a list of possible symptoms.

If any side effect occurs, the infusion must be stopped.

How to store Sodium Chloride Intravenous Infusion BP 0.9% w/v
Keep this medicine out of sight and reach of children.
Store below 30°C.

CRITICAL POINTS OF CARE FOR SAFE ADMINISTRATION AND USE OF INTRAVENOUS SOLUTIONS WHICH FORM AN INTEGRAL PART OF THE DRUG DELIVERY SYSTEM

What material is the container of the fluid made of?
The container is made from pharmaceutical grade Low Density Poly-Ethylene complying with Pharmacopoeial requirements of plastics for packaging of preparations for parenteral use. The inert material offers drug compatibility. As the container material does not contain any additives there is no leaching of any substance into the drug solution.

Is the fluid container collapsible?
Yes, the fluid container is self collapsible. A closed drug delivery system is achieved as the container design allows for easy fluid flow dynamics thus avoiding the risky unconventional local /regional practice of providing a flow vent in a non-collapsible container with a needle pierced through the container wall in a risky hospital environment prone to infectious disease carriers.

What container closure system is provided?
The bottle is closed system container. This system provides two injection ports and resealing ports for the infusion giving set thus giving a high level of drug delivery and administration practice.

Who makes Sodium Chloride Intravenous Infusion BP 0.9% w/v?
Sodium Chloride Intravenous Infusion BP 0.9% w/v is manufactured by

B. BRAUN PHARMACEUTICALS EPZ LTD.
L.R. No. 18474/84 Athi River
P.O. Box 51200-00100
Nairobi, Kenya

Product registration No. in Kenya: H2013/CTD1340/271

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Useful Handling Tips for Closed System Container

Infusion Administration

Opening

Peel off the covering foil of port.

Injection Port

Swab injection port.

Handling during spiking

When inserting an infusion set or a needle into the port, grip the neck of the Closed System Container to stabilize the container or leave it free standing.

Using infusion sets

When the set is removed, the port on Closed System Container reseals automatically.
Avoid rotating the spike when piercing the port.

No venting required

During infusion, Closed System Container collapses completely without any need for ventilation.

Collapsed Closed System Container

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