

PACKAGE LEAFLET: INFORMATION FOR THE USER

SODIUM CHLORIDE 0.9% w/v SOLUTION FOR INJECTION

This leaflet will provide you with important information about your medicine. Please read it carefully before your medicine is administered. The leaflet contains a summary but not all of the information about Sodium Chloride 0.9% w/v Solution for Injection. If you require any further information or if you are unsure about anything, ask your physician or pharmacist.

ABOUT YOUR MEDICINE

Sodium Chloride 0.9% w/v Solution for Injection is a clear, colourless sterile solvent for parenteral use. Each 1ml of this solvent contains 9mg of the active ingredient, sodium chloride. Each 1ml of sterile solution for injection contains 0.15millimoles of Na⁺ and Cl⁻ ions. 2ml of sterile solution for injection contains 0.3millimoles of Na⁺ and Cl⁻ ions. 5ml of sterile solution for injection contains 0.75millimoles of Na⁺ and Cl⁻ ions. 10ml of sterile solution for injection contains 1.5millimoles of Na⁺ and Cl⁻ ions. Other ingredients: Water for Injections and Hydrochloric Acid (for pH adjustment).

Pack sizes: 2ml, 5ml and 10ml in glass ampoules (packs of 10 ampoules). (Not all pack sizes may be marketed.)

Type of medicine: Sodium Chloride 0.9% w/v Solution for Injection is an isotonic saline solution.

Being isotonic means that the body cells bathed in the solution will neither shrink nor swell.

Holder of Product Authorisation:

Mercury Pharmaceuticals (Ireland) Ltd,

4045, Kingswood Road, City West Business Park, Co Dublin, Ireland

Manufacturer: Lomapharm Rudolf Lohmann GmbH KG, Langes Feld 5, 31860, Emmerthal, Germany.

PA No.: 73/105/1 (2ml, 5ml and 10ml glass ampoules).

USES

Sodium Chloride 0.9% w/v Solution for Injection may be used to prevent or to treat certain types of salt and fluid imbalances that may occur in the body.

The solution may be used to dilute or to prepare some drugs for use. It may also be used for irrigation (e.g. to wash out wounds).

BEFORE YOU RECEIVE YOUR MEDICINE

If you have any of the following conditions, tell your physician before you receive this medicine:

- heart disease
- a kidney disorder
- toxaemia of pregnancy
- a build-up of excess fluid in the body (e.g. swollen ankles).

You should also tell your physician if you are taking any medicines containing sodium salts. This medicinal product contains 0.15mmol sodium per ml which is 0.3mmol sodium for the 2ml ampoules, 0.75mmol sodium for the 5ml ampoules, and 1.5mmol sodium for the 10ml ampoules. To be taken into consideration by patients on a controlled sodium diet.

HOW YOUR MEDICINE IS ADMINISTERED

When used to prevent or to treat fluid or salt imbalances, Sodium Chloride 0.9% w/v Solution for Injection is administered into a vein. Your physician will decide on the appropriate dosage for your particular condition.

When used to dilute or to prepare another medicine for use, the method of administration will depend on the particular medicine being prepared.

What to do in case of a missed dose or an overdose If you think that you may have missed a dose or that you have been given too much of this medicine, tell your physician.

AFTER YOU RECEIVE YOUR MEDICINE

Sodium Chloride 0.9% w/v Solution for Injection does not produce unwanted effects when it is administered correctly. If you do notice any unusual symptoms during treatment, tell your physician.

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 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.

STORING THIS MEDICINE

Do not use Sodium chloride injection after the expiry date which is stated on the carton and ampoule label after Exp. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the ampoules in the outer carton in order to protect from light.

The solution should not be used if the ampoule is damaged or if the contents are discoloured or contain any visible particles.

Keep out of the reach and sight of children.

Once opened, use immediately.

If only part used, discard the remaining solution.

For single use only.

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