

Package leaflet: Information for the user

B. Braun Melsungen AG · 34209 Melsungen, Germany

0.9% w/v Sodium Chloride Injection BP

Sodium chloride

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 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 0.9% w/v Sodium Chloride Injection BP is and what it is used for
2. What you need to know before you take 0.9% w/v Sodium Chloride Injection BP
3. How to use 0.9% w/v Sodium Chloride Injection BP
4. Possible side effects
5. How to store 0.9% w/v Sodium Chloride Injection BP
6. Contents of the pack and other information

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

This medicine is a solution of sodium chloride administered to you by injection.

It contains sodium chloride at a concentration similar to the concentration of salts in your blood.

It is used to deliver medicinal products.

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

Do not use 0.9% w/v Sodium Chloride Injection BP if you have:

- very high levels of sodium in your blood (severe hypernatraemia)
- very high levels of chloride in your blood (severe hyperchloraemia)

Warnings and precautions

Talk to your doctor or pharmacist before using 0.9% w/v Sodium Chloride Injection BP.

Take special care with 0.9% w/v Sodium Chloride Injection BP if you have:

- abnormally high level of sodium in the blood (hypernatraemia)
- abnormally high level of chloride in your blood (hyperchloraemia)

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

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

If you are taking drugs that help increase the sodium levels in your blood (corticosteroids, certain types of anti-inflammatory agents) and you are given 0.9% w/v Sodium Chloride Injection BP, you may experience swelling (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 or pharmacist for advice before taking this medicine.

Pregnancy

As the concentrations 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.

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. 0.9% w/v Sodium Chloride Injection BP can be used during breast-feeding, if required.

Driving and using machines

0.9% w/v Sodium Chloride Injection BP has no influence on the ability to drive and use machines.

3. How to use 0.9% w/v Sodium Chloride Injection BP

The medicinal product is used to prepare injections (preparations administered by a syringe). It will be administered into your vein (intravenous use), into your muscle (intramuscular use) or under your skin (subcutaneous use).

Dosage

The amount of the medicinal product that you will be given depends on the instructions given for the drug to be dissolved or diluted.

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

An overdose could lead to abnormally high fluid, sodium and chloride levels in your blood and high levels of acidic substances in your blood (your blood getting sour).

In such a case your injection 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.

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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 0.9% w/v Sodium Chloride Injection BP

Keep this medicine out of the sight and reach of children. This medicinal product does not require special precautions for storage.

Do not use this medicine after the expiry date which is stated on the labels on the ampoule and on the outer carton. The expiry date refers to the last day of that month.

Do not use if the solution is not clear and colourless or the container or its closure show visible signs of damage.

After first opening:

The product must be used immediately after opening the container.

After preparation of the ready-to-use mixture:

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 0.9% w/v Sodium Chloride Injection BP contains

- The active substance is sodium chloride.
Each ml of the solution contains 9 mg of sodium chloride.
- The other ingredient is water for injections.

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

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

It comes in:

- Polyethylene ampoules, contents: 10 ml, 20 ml available in packs of 20 x 10 ml, 20 x 20 ml
- Polypropylene ampoules, contents: 10 ml, 20 ml available in packs of 50 x 10 ml, 100 x 10 ml, 50 x 20 ml, 100 x 20 ml

Marketing Authorisation Holder and Manufacturer

PA Holder:
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PA 0179/002/013

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