

Sodium Chloride 0.9% Solution for injection

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 further questions, please ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is "Sodium Chloride 0.9% Solution for injection" but it will be referred to as Sodium Chloride 0.9% throughout this leaflet.

What is in this leaflet

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

1. WHAT SODIUM CHLORIDE 0.9% IS AND WHAT IT IS USED FOR

Sodium Chloride 0.9% is a solution for injection and is used as a solvent and carrier for drugs. It can be given by the intravenous, intramuscular or subcutaneous route.

This product belongs to the "Electrolyte Solutions" group and is distributed under medical prescription.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SODIUM CHLORIDE 0.9%

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sodium Chloride 0.9% Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium chloride 0.9%w/v

Electrolytes:

Na⁺ 154 mmol/l

Cl⁻ 154 mmol/l

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for Injection

A clear colourless solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Chloride 0.9% Solution for injection is used as a solvent and carrier solution for injectable drugs.

4.2 Posology and method of administration

Posology

As required

Method of administration

Intravenous, intramuscular or subcutaneous use

4.3 Contraindications

None stated.

4.4 Special warnings and precautions for use

If Sodium Chloride 0.9% Solution for injection is to be administered subcutaneously be aware that any additions to the isotonic normal saline solution could render it hypertonic and thus cause pain at the injection site.

Do not use Sodium Chloride 0.9%:

- If you are allergic to sodium chloride or any of the other ingredients of this medicine (listed in section 6).

Other medicines and Sodium Chloride 0.9%

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

The solution of Sodium Chloride 0.9% shows no incompatibilities with other medicinal products.

Sodium Chloride 0.9% with food and drink

Sodium Chloride 0.9% is not known to have any interactions when given at the same time as food and drink.

Pregnancy and breast-feeding

Please ask your doctor or your pharmacist before being administered this medicine.

If a correct and controlled dose of Sodium Chloride 0.9% is administered, no effects on pregnant women and during lactation are expected.

Driving and using machines

There is no evidence that Sodium Chloride 0.9% solution may affect the ability to drive or to use machines.

3. HOW TO USE SODIUM CHLORIDE 0.9%

Sodium Chloride 0.9% will be given to you by an appropriately trained professional.

Sodium Chloride 0.9% will be administered by intravenous, intramuscular or subcutaneous route.

It does not contain any type of preservative or germicide, hence, opened ampoules should be immediately discarded once used.

The amount used will vary depending on the concentration at which the drug to be dissolved is to be administered.

Your doctor will inform you of the duration of your treatment.

If you have received more Sodium Chloride 0.9% than you should:

Given the product's nature, if its indication and administration are correct and controlled, there is no risk of overdose.

If you have been given more Sodium Chloride 0.9% than you should have had, inform your doctor immediately.

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4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

None stated

4.7 Effects on ability to drive and use machines

No studies on the ability to drive and use machines have been performed.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

No particulars stated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: B05XA03

Sodium chloride 0.9% solution shows the same osmotic pressure as body fluids.

The isotonic solution of sodium chloride is a suitable vehicle for administration of a large number of drugs and electrolytes.

5.2 Pharmacokinetic properties

Sodium and chloride electrolytes distribute, primarily, in the extracellular fluid. Because the physiological saline solution is isotonic, its administration will not produce a change in the osmotic pressure of the extracellular fluid, whereby water will not pass into the intracellular compartment and both ions will practically enter the cell.

5.3 Preclinical safety data

Safety of sodium chloride isotonic solutions is adequately recognised in the fluid therapy field worldwide, thanks to a wide experience available in the use of this solution as a restorer of the hydro-electrolytic balance.

4. POSSIBLE SIDE EFFECTS

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

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 Yellow Card System at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SODIUM CHLORIDE 0.9%

Keep this medicine out of the sight and reach of children.
For single use only.

To be used immediately after the ampoule is opened.
Do not use after expiry date which is stated on the carton after EXP.
The expiry date refers to the last day of that month. Any unused solution should be discarded.

Use only clear, particle-free solutions and undamaged containers.
Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sodium Chloride 0.9% contains

Each 1 ml contains 9 mg of sodium chloride.

The other ingredients are water for injection and traces of sodium hydroxide and hydrochloric acid.

What Sodium Chloride 0.9% looks like and contents of the pack.

Sodium Chloride 0.9% is a clear colourless, particle-free solution. It is available in the following formats:



6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection.
Sodium hydroxide.
Hydrochloric acid.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

a) Shelf life of the product as packaged for sale:

Shelf life of the pharmaceutical product: 2 years

b) Shelf life after first opening of the container:

The product should be used immediately after opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Low density polyethylene ampoules (LDPE).

- Carton with 20 ampoules of 5 ml
- Carton with 20 ampoules of 10 ml
- Carton with 20 ampoules of 20 ml
- Carton with 50 ampoules of 10 ml
- Carton with 100 ampoules of 10 ml

6.6 Special precautions for disposal and other handling

It is not necessary to sterilise the bottle before its opening.

It is not necessary to use any cutting element to open the ampoule.

Once the ampoule is opened the top of it can perfectly be adjusted to the syringe cone (cone Luer), with which it is necessary to use the needle.

Handling instructions:

To break off a single ampoule, twist one ampoule against the remaining ampoules of the pack without touching the head and neck of the ampoules (1). Shake the ampoule with one single movement as shown below in order to remove the liquid kept in the cap (2). To open the ampoule, twist the ampoule body and ampoule head in opposite directions until the neck breaks off (3). Connect the ampoule to the luer-syringe or luer-lock syringe as shown in figure (4).

Carton with 20 ampoules of 5 ml.
Carton with 20 ampoules of 10 ml.
Carton with 20 ampoules of 20 ml.
Carton with 50 ampoules of 10 ml.
Carton with 50 ampoules of 10 ml.
Carton with 100 ampoules of 10 ml.

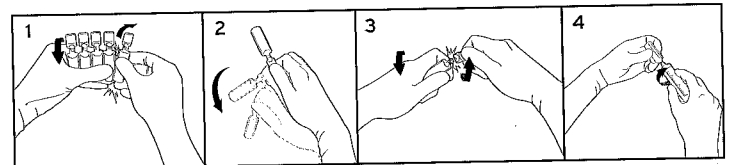
Marketing Authorisation Holder

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT.
UK.

Manufacturer

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08005-Barcelona (ESPAÑA)

This leaflet was last revised in 10/2018



The solution does not contain any type of preservative or bactericide, so open and unused ampoules should be discarded immediately.

7. MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT
UK

8. MARKETING AUTHORISATION NUMBER

PL 08828/0178

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 30/08/2007

Date of last renewal:

10. DATE OF REVISION OF THE TEXT

10/2018