

## Patient Information Leaflet

### Sodium Chloride 0.9% w/v Injection BP

#### Sodium Chloride

**Please read all of this leaflet carefully. It includes important information on how you should take this medicine correctly and safely.**

- Keep this leaflet. You may need to read it again.
- If you are the parent of a child who is to be given this medicine, read the leaflet replacing 'you' with 'your child' throughout.
- This medicine is prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or you notice any side effects not listed in the leaflet please tell your doctor, nurse or pharmacist.
- If you have any further questions, please ask your doctor, nurse or pharmacist.

**The name of your medicine is Sodium Chloride 0.9% w/v Injection BP.**

*In the rest of this leaflet Sodium Chloride 0.9% w/v Injection is called Sodium Chloride.*

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#### **In this leaflet:**

1. What Sodium Chloride is and what it is used for
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  3. How to take Sodium Chloride
  4. Possible side effects
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#### **1. What Sodium Chloride is and what it is used for**

Sodium Chloride is a type of medicine called an electrolyte. It is a sterile salt liquid which can be used for a number of different reasons as it is very similar to your body fluids.

The main use for Sodium Chloride injection is to dissolve or dilute other medicines so they can be given as an injection or an infusion (a drip) into veins, muscles or other tissues in the body. Sodium Chloride can also be used for preparation for a number of surgical and medical procedures as follows:

- to clean out catheters (small devices put in your vein to inject your medicine).
- as a priming solution to fill intravenous lines (long tubes which are connected to your veins) This is to make sure there is no air being injected such as during haemodialysis (a procedure to clean blood when you have kidney disease).
- as a priming solution at the beginning and end of blood transfusions without causing damage to the blood cells.

Sodium Chloride can also be added to other medicines such as infusions (drips) for example sugar solutions. In this case, Sodium Chloride works as an electrolyte to help keep the water levels in different parts of your body in the right balance.

## 2. Before you take Sodium Chloride

The doctor or nurse giving you this medicine will ask some questions about you. They need the following information before you have this medicine for the first time.

### **Do not take Sodium Chloride**

- If you have hypernatremia.
- If you have hyperchloremia.

### **Take special care with Sodium Chloride**

Tell your doctor or nurse before treatment starts if:

- You have problems with your heart.
- You have problems with your blood pressure.
- You have problems with your kidneys.
- You have problems with sodium retention.

Please make sure you read the leaflets for all your medicines, as Sodium Chloride is sometimes added to another medicine such as to dissolve or dilute it.

### **Taking other medicines**

Please tell your doctor about any medicines you may be taking or have recently been taking. Remember also any medicines you may be taking that do not need a prescription.

If you are taking any of the following medicines it is very important to tell your doctor:

- Corticosteroids such as cortisone, hydrocortisone, prednisone, prednisolone, betamethasone.

### **Pregnancy and breast-feeding**

Sodium Chloride is not known to cause problems during pregnancy or breast-feeding.

As Sodium Chloride is sometimes given with other medicines, it is important that:

- If you are pregnant, or think you may be pregnant you must tell your doctor.
- If you are breast-feeding you must tell your doctor.

Your doctor will advise you if you should have this medicine.

## 3. How to take Sodium Chloride

A doctor or a nurse will usually give you this medicine.

Your doctor or nurse will use the correct amount of Sodium Chloride depending on what it is being used for.

Your doctor will decide the amount (dose) of your medicine that you should receive and how long you will need to take it for. The dose will depend on what Sodium Chloride is being used for such as to dissolve or dilute another medicine or as a priming solution.

### **If you take more Sodium Chloride than you should**

A doctor or a nurse will usually give you this medicine. If you think you may have received too much medicine, please tell your doctor or nurse at once.

As this medicine comes in a small volume (maximum 20 millilitres per container), it is unlikely that you will take too much.

Sodium Chloride is sometimes given with other medicines, so make sure you read the leaflets for all your medicines.

**Please read the other side of this leaflet.**

**If you forget to take Sodium Chloride**

A doctor or a nurse will usually give you this medicine. If you think you have missed a dose, please tell your doctor or nurse.

If you have any further questions on the use of your medicine, ask your doctor, nurse or pharmacist.

#### 4. Possible side effects

Like all medicines, Sodium Chloride can cause side effects, but not everyone gets them. The expected benefit of your medicine will usually be greater than the risk of you suffering any harmful side effects.

Side effects known for Sodium Chloride when used for dissolving and diluting other medicines or when it is used as a priming solution are too much sodium in your blood, too much chloride in your blood.

Remember that you may also get side effects from the other medicines that Sodium Chloride is being used to dissolve or dilute. Make sure you read the leaflets for all your medicines.

If you notice any troublesome symptoms which you think may be side effects, please tell your doctor, nurse or pharmacist.

**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

**For UK:** Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

**For IE:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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

#### 5. How to store Sodium Chloride

Keep your medicine out of the reach and sight of children.

Do not use your medicine after the expiry date (EXP) given on the carton and the label on the plastic container (ampoule). The expiry date is the last day of the month written on the packaging.

This medicinal product does not require any special storage conditions.

Only use your medicine if it is a clear and colourless liquid. Open it and use it straight away.

Any unused product should be discarded after opening.

Give any leftover medicine to your doctor, nurse or pharmacist. If you do this, it will help protect the environment. Do not put it down the drain or in the dustbin.

## 6. Further information

### What Sodium Chloride contains

The active medicine is Sodium Chloride. The other ingredient is Water for Injections. The medicine contains 0.9 %w/v (9 mg per mL) of Sodium Chloride.

### What Sodium Chloride looks like

Sodium Chloride is a clear, colourless liquid.

### Contents of the pack

Each plastic ampoule contains 5 mL (millilitres), 10 mL or 20 mL of your medicine. 20 and 50 ampoules come in boxes of 5 mL. 20, 50 and 100 ampoules come in boxes of 10 mL and 20 ampoules come in a box of 20 mL. Not all pack sizes may be available.

### Marketing Authorisation Holder and Manufacturer

**Marketing Authorisation Holder:** Noridem Enterprises Ltd., Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.

**Manufacturer:** DEMO S.A., Pharmaceutical Industry, 21<sup>st</sup> km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece, **T:** +30 210 8161802, **F:** +30 210 8161587

### This medicinal product is authorised in the Member States of the EEA under the following names:

|                 |                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------|
| Denmark:        | Natriumchlorid "Noridem", solvens til parenteral anvendelse/injektionsvæske, opløsning 9mg/mL        |
| Germany:        | Natriumchlorid Noridem 0.9% Injektionslösung                                                         |
| Ireland:        | Sodium Chloride 0.9% (w/v) Injection BP                                                              |
| Norway:         | Natriumklorid Noridem 9mg/mL injektjonsvæske, oppløsning "Noridem"                                   |
| Portugal:       | Cloreto de sódio Noridem, 9mg/mL, Solução injectável                                                 |
| Sweden:         | Natriumklorid Noridem 9mg/mL injektionsvätska, lösning                                               |
| Spain:          | Cloruro de sodio Serracliclinics 9 mg/ml (0,9%), solución inyectable                                 |
| United Kingdom: | Sodium Chloride 0.9% (w/v) Injection BP                                                              |
| Austria:        | Natriumchlorid Noridem 0.9% Injektionslösung oder Lösungsmittel zur Herstellung von Parenteralia     |
| Greece:         | SODIUM CHLORIDE 0,9%/NORIDEM, Διαλύτης για παρεντερική χρήση 9mg/mL                                  |
| Netherlands:    | Natriumchloride Noridem 0.9%, oplossing voor injectie en oplosmiddel voor parenteraal gebruik 9mg/mL |

**This leaflet was last revised in May 2020.**