

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sterile Sodium Chloride Concentrate 30% w/v

Concentrate for Solution for Infusion
Sodium Chloride

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse

In this leaflet:

1. What Sterile Sodium Chloride Concentrate is and what it is used for
2. Before you are given Sterile Sodium Chloride Concentrate
3. How Sterile Sodium Chloride Concentrate will be given
4. Possible side effects
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6. Further information

1. What Sterile Sodium Chloride Concentrate is and what it is used for

Sodium Chloride belongs to a group of medicines called electrolytes. The balance of the electrolytes in the body is essential for normal function of our cells and our organs.

Sterile Sodium Chloride Concentrate, when diluted, is used to put electrolytes back into your body. Electrolytes are lost through too much sweating, prolonged diarrhoea or vomiting. This can eventually lead to excess water loss from the body (dehydration).

2. Before you are given Sterile Sodium Chloride Concentrate

You should not be given Sterile Sodium Chloride Concentrate if:

- you are allergic (hypersensitive) to Sodium Chloride

If you are unsure about being given this medicine or you have any questions, talk to your doctor or nurse.

Take special care with Sterile Sodium Chloride Concentrate if:

- you have heart disease or other heart problems
- you suffer from water retention
- you suffer from high blood pressure
- you suffer kidney problems
- you suffer from liver problems
- you suffer from water on the lungs
- you suffer from a serious complication of pregnancy known as pre-eclampsia (the symptoms of which include 2 or more of the following; high blood pressure, fluid retention or protein in the urine).
- you suffer from diabetes

Special care should be taken when Sterile Sodium Chloride Concentrate is given to children and the elderly.

If any of the above apply to you or your child please tell your doctor before you are given Sterile Sodium Chloride Concentrate

Taking other medicines

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Medicines which may interact with Sterile Sodium Chloride Concentrate include:

- streptomycin sulphate, a medicine used to treat tuberculosis and other bacterial infections

If you have any doubts about whether this medicine should be administered to you, consult your doctor or nurse.

Pregnancy and breast-feeding

Sterile Sodium Chloride Concentrate is usually suitable for use whilst you are pregnant or breast-feeding however you should ask your doctor for advice before you are given this medicine.

Driving and using machines

There are no known effects of having Sterile Sodium Chloride Concentrate on driving or using machines.

3. How Sterile Sodium Chloride Concentrate will be given

Adults, the elderly and children

Your doctor will decide the amount of Sterile Sodium Chloride Concentrate you need depending on your age, weight and general health. You will be given Sterile Sodium Chloride Concentrate into a vein (intravenously) once it has been diluted.

If you are given more Sterile Sodium Chloride Concentrate than you should be

As this medicine will be given to you whilst you are in hospital, it is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, Sterile Sodium Chloride Concentrate can cause side effects, although not everybody gets them.

Possible side effects include:

- feeling or being sick
- stomach pains
- diarrhoea
- feeling thirsty
- a dry mouth or eyes
- sweating
- fever
- a fast or irregular heartbeat
- kidney problems
- water on the lungs
- water retention (the symptoms of which include swelling of the ankles or shortness of breath)
- headache
- dizziness
- feeling restless or irritable
- feeling weak
- muscle twitching and stiffness
- feeling sleepy or confused
- fits
- breathing difficulties

Infants may experience the following side effects:

- fits
- breathing quickly
- flared nostrils (caused by difficulty breathing)
- coma

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. How to store Sterile Sodium Chloride Concentrate

Keep out of the reach and sight of children.

You should not be given Sterile Sodium Chloride Concentrate after the expiry date which is printed on the carton and ampoule label after EXP. The doctor or nurse will check that the expiry date on the label has not been passed before administering the injection to you. The expiry date refers to the last day of that month.

Store below 25°C

The ampoule containing the injection will only be used for you and if any injection is left over the doctor/ nurse will dispose of it.

6. Further Information

What Sterile Sodium Chloride Concentrate contains

The active substance is Sodium Chloride 300mg/ml
The other ingredient is water for injections. Sterile Sodium Chloride Concentrate may also contain hydrochloric acid or sodium hydroxide.

What Sterile Sodium Chloride Concentrate looks like and contents of the pack

Sterile Sodium Chloride Concentrate 30% w/v, Concentrate for Solution for Infusion is a clear colourless solution supplied in 2ml and 10ml clear glass ampoules. Each pack contains 10 ampoules.

Manufacturer

Martindale Pharmaceuticals, Bampton Road, Harold Hill, Romford, Essex, RM3 8UG, UK.

Marketing Authorisation Holder in Ireland

In Ireland the product is marketed by Martindale Pharmaceuticals, Romford, RM3 8UG, UK.

The PA holder is Marcarthys Laboratories Ltd, Bampton Road, Harold Hill, Romford, Essex, RM3 8UG, UK.

Marketing Authorisation Holder in UK

Martindale Pharmaceuticals Ltd, Bampton Road, Harold Hill, Romford, Essex, RM3 8UG, UK.

If you would like any more information, or you would like the leaflet in a different format, please contact Medical Information at the above address.

This leaflet was last approved in Nov/2010

Product License Number: PL 01883/6158
PA274/01/01

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MARTINDALE PHARMA

ORACLE code: **C91327**

Description: PIL Sterile Sodium Chloride Concentrate Injection 30%w/v 10ml

Market: UK

PCI: 0414

Replaces code: C91297

Template/style number: 170 x 296mm

Colours: PMS Black PMS

PMS PMS

Min Point size (legal text): 8pt

Version number: 01 Date: 17/04/12 By: HM

Date of previous revision: 16/04/12 (C91327-01)

EAN Barcode (if applicable):

Artwork Dept

To confirm that all artwork checks have been completed prior to circulation

Name:

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Quality

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Name:

Signature:

Date:

Comments:

Software/platform: InDesign CS5

Linked graphics:

Fonts: Myriad Pro

File name: **C91327-01**

Component specifics:

Nominal Dimensions: 170 x 296mm

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