

Package leaflet: Information for the user

Sodium chloride 5mmol/ml Oral Solution

Read all of this leaflet carefully before you start taking 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.

The name of your medicine is Sodium chloride 5mmol/ml Oral Solution but it will be referred to as Sodium chloride throughout this leaflet.

What is in this leaflet:

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

1. What Sodium chloride is and what it is used for

Sodium chloride is the chemical name for salt. Sodium is an electrolyte that regulates the amount of water in your body. Sodium also plays a part in transmission of nerve impulses and muscle contractions.

Sodium chloride is used for the treatment of sodium chloride deficiency.

Electrolytes

Electrolytes are minerals in the cells and blood that conduct electrical impulses and messages. These minerals can be lost through sweating, excessive vomiting, diarrhoea and excessive exercise.

When these electrolytes are not replaced, conditions such as muscle cramping and weakness will arise.

2. What you need to know before you take Sodium chloride

Do not take Sodium chloride:

- ▶ If you have high sodium levels
- ▶ If you have oedema
- ▶ If you have heart disease
- ▶ If you have a disorder producing more aldosterone hormone than normal
- ▶ If you have a condition where the heart needs help to maintain blood circulation
- ▶ If you are taking medication that causes salt and water loss from the body, usually if you have fluid retention or heart failure or have high blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sodium chloride

- ▶ If you have high blood pressure
- ▶ If you have heart failure
- ▶ If you have fluid build-up in the lungs or lower limbs
- ▶ If you have kidney problems
- ▶ If you have pre-eclampsia (high blood pressure during pregnancy)
- ▶ If you are on a low-salt diet.

Other medicines and Sodium chloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines and dietary supplements. This is because Sodium chloride can affect the way some other medicines work and some medicines can have an effect on the way Sodium chloride works.

In particular, tell your doctor if you are taking any of the following:

- ▶ Lithium
- ▶ Calcium
- ▶ Atrial Natriuretic Peptides
- ▶ Insulin
- ▶ Aldosterone
- ▶ Diuretics (water tablets)
- ▶ Corticosteroids (e.g. prednisone) or corticotrophin. These may make side effects worse.

Sodium chloride with food and drink

Sodium chloride may be taken with or without food.

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.

Sodium chloride is not expected to have an adverse effect on pregnancy or breast-feeding.

Driving and using machines

Sodium chloride does not affect the ability to drive or operate machinery.

3. How to take Sodium chloride

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Doses

Chronic salt depletion

Adults: 8ml-16ml (40-80mmol) daily along with suitable fluid intake at intervals as directed by your doctor.

Children (1month - 18 years):

The doctor will adjust the dose as per child's body weight to their needs. In infants the dose may be administered in breast milk or formula milk.

Neonates: 3 to 5 mmol/kg (0.6 to 1 ml per kg) daily in divided doses. Dosages can be adjusted according to patient requirements.

Warning: This product must be diluted in drinks, breast milk or formula feed before it is administered.

Kidney Impairment: Dose adjustment may be necessary.

Route and method of administration:

This medicinal product must be taken orally.

Sodium chloride may be diluted in a glass of water or baby's bottle.

Use the measuring pipette or syringe provided in the pack to deliver the required dose.

If you take more Sodium chloride than you should

If you take more Sodium chloride than you should, tell your doctor or go to your nearest hospital casualty department straight away. Take the medicine pack with you. Overdose may result in thirst, dry mouth due to reduced salivation, dry eyes due to reduced tear secretion, fever, increased heart beat, changes in blood pressure, headache, dizziness, restlessness, irritability, weakness and muscle twitching and rigidity. In extreme cases it may lead to dehydration of brain resulting in feeling sleepy, convulsions, coma, respiratory failure and death.

If you forget to take Sodium chloride

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

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.

Rapid or over correction of sodium levels may lead to a life-threatening condition known as osmotic demyelination syndrome which might result in weakness of all limbs and cognitive changes.

Seek medical attention immediately if any of these severe side effects occur:

- ▶ Severe allergic reactions (rash, hives, difficulty in breathing, tightness in chest, swelling of mouth, face, lips, tongue)
- ▶ Confusion, weakness
- ▶ Seizures
- ▶ Muscle twitching.

Other side effects include:

- ▶ Swollen tongue
- ▶ Nausea
- ▶ Vomiting
- ▶ Diarrhoea
- ▶ Stomach cramps
- ▶ Thirst
- ▶ Dry mouth and eyes

- ▶ Sweating
- ▶ Fever
- ▶ Irritability
- ▶ Weakness
- ▶ Headache
- ▶ Dizziness, restlessness
- ▶ Convulsions
- ▶ Coma and death
- ▶ Hypotension or hypertension
- ▶ Excess salt in your blood
- ▶ Fast heart beat
- ▶ Fluid build-up in the lungs or limbs, shortness of breath.

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.

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 Website: www.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 this medicine out of the sight and reach of children.
- ▶ Do not use this medicine after the expiry date which is stated on the carton and bottle label after 'Exp'. The expiry date refers to the last day of that month.
- ▶ This medicinal product does not require any special storage conditions.
- ▶ Discard 07 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- ▶ Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sodium chloride contains

Each ml of oral solution contains 5mmol (292.2mg) sodium chloride.

The other ingredient is purified water.

What Sodium chloride looks like and contents of the pack

Sodium chloride is a clear, colourless solution supplied in amber PET bottles with a tamper-evident child-resistant plastic screw cap.

The 100ml pack containing a 1ml oral syringe with 0.01ml graduation mark and an adaptor for the syringe.

or

The 100ml pack containing a 4ml oral pipette with 0.1ml graduation mark.

Marketing Authorisation Holder:

Syri Pharma Limited t/a Thame Laboratories
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Manufacturer:

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OR

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POM

If this leaflet is hard to see or read, please call +353 1437 8830 for help.

This leaflet was last revised in 08/2022.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

UK(NI) and IE: Sodium chloride 5mmol/ml Oral Solution