

Sodium Chloride 1 mmol/ml Oral Solution

Please read all of this leaflet carefully before your infant is given this medicine.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask the hospital doctor who is looking after your infant.
- If you notice any side effects, talk to your doctor. This includes any possible side effects not listed in the leaflet. See section 4.

What is in this leaflet:

1. What Sodium Chloride 1 mmol/ml Oral Solution is and what it is used for
2. What you need to know before your infant is given Sodium Chloride 1 mmol/ml Oral Solution
3. How Sodium Chloride 1 mmol/ml Oral Solution is given
4. Possible side effects
5. How Sodium Chloride 1 mmol/ml Oral Solution is stored
6. Contents of the pack and other information

1. What Sodium Chloride 1 mmol/ml Oral Solution is and what it is used for

Sodium Chloride 1 mmol/ml Oral Solution is a source of sodium chloride used to correct hyponatraemia (low blood sodium levels) in infants. Sodium chloride is found widely in the body, and is important to normal body functions.

2. What you need to know before your child is given Sodium Chloride 1 mmol/ml Oral Solution

Your child, should not be given this medicine if there is known hypersensitivity (allergy) to any of the ingredients listed in Section 6.

Warnings and Precautions.

Your child should not be given this medicine if they have:

- Fluid retention.
- Heart failure.
- Intestinal obstruction.
- Aldosteronism (a condition where too much aldosterone [a hormone] is produced).
- Liver or kidney disease.

If you think you are affected by any of these consult your doctor or pharmacist before taking this medicine.

Other medicines and Sodium Chloride 1 mmol/ml Oral Solution

You should tell your child's doctor if they are having any medicines, including those obtained without a prescription.

Sodium Chloride 1 mmol/ml Oral Solution Contains Sodium.

Sodium Chloride 1 mmol/ml Oral Solution contains 23 mg sodium per 1 ml of the solution. Equivalent to 58.44 mg of sodium chloride (salt) in 1 ml of the solution.

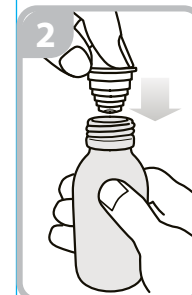
3. How Sodium Chloride 1 mmol/ml Oral Solution is given.

Always give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Sodium Chloride 1 mmol/ml Oral Solution is given by mouth.

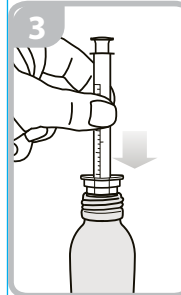
How the medicine should be given



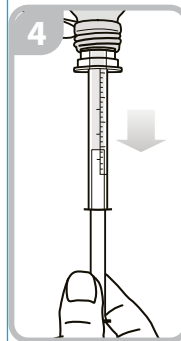
Remove the cap from the bottle by pressing down firmly and turning anticlockwise.



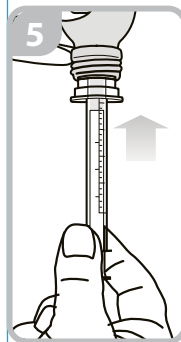
Hold the button tightly on a firm surface and push the bottle adaptor into the neck of the bottle. Push it down until it is flush with the top of the bottle.



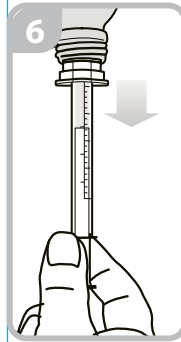
Take the syringe and put it in the small hole in the bottle adaptor.



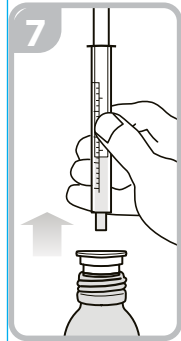
To fill the syringe turn the bottle with the syringe attached upside down. Gently pull the plunger down drawing the medicine into the syringe.



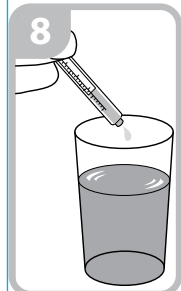
If there is an air bubble in the syringe gently push the plunger back upwards until the air bubble is expelled back into the bottle.



Then pull the plunger down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor.



Turn the bottle the right way up and remove the syringe.



Dilute the medicine by emptying the syringe contents into a drink, breast milk or formula. Do not administer the medicine without first diluting.

Continued overleaf

The dose can vary according to need, and your doctor will normally advise how much to give. In the case of infants this will normally be calculated based on bodyweight in kg. As a guide:

Infants: 3 to 5 mmol/kg (3 to 5 ml of Sodium Chloride 1 mmol/ml Oral Solution 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.

Shake the bottle before use

If your child is given too much:

If your child is accidentally given too much Sodium Chloride 1 mmol/ml Oral Solution it should not be harmful. However, the side effects described below may become more noticeable. If a large excess is given, your child should see a doctor or be taken to hospital straight away. Take this medicine with you. It is particularly important to do this for the very young, or if the child in your care has severe liver or kidney disease. If signs of side effects are noticed, please tell your doctor.

4. Possible side effects

Like all medicines, Sodium Chloride 1 mmol/ml Oral Solution can cause side effects, but these are not normally a problem when this medicine is used as described.

Serious Side Effects

If your child experiences any of the following reactions stop taking Sodium Chloride 1 mmol/ml Oral Solution and contact your doctor IMMEDIATELY:

- Thirst (Not always obvious in children, especially very young infants)
- Lethargy
- Weakness
- Irritability
- Confusion
- Twitching

In more extreme cases this can lead to:

- Seizures
- Coma

Reporting of side effects

If you notice any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via the yellow card scheme, Website: <https://yellowcard.mhra.gov.uk>. By reporting side effects you can help provide more information on the safety of this medicine

5. How Sodium Chloride 1 mmol/ml Oral Solution is stored

Store below 25°C

Keep this bottle tightly closed

Keep out of reach and sight of children

Store in the original container and carton

Do not use this medicine after the expiry date which is stated on the carton and bottle label, or if the solution appears discoloured or cloudy.

Use within 1 month of first opening.

6. Contents of the pack and other information

What Sodium Chloride 1 mmol/ml Oral Solution contains
The active substance is sodium chloride 1 mmol/ml. Other ingredients are potassium sorbate (E202), citric acid (E330) and purified water.

What this product looks like and contents of the pack

Sodium Chloride 1 mmol/ml Oral Solution is a clear, colourless liquid in a 100 ml amber glass bottle. Each pack contains one bottle of solution, a 5ml dosing syringe and a syringe adaptor to fit into the bottle when measuring the dose.

Marketing Authorisation Holder

Macarthy's Laboratories Limited T/A Martindale Pharma
Bampton Road
Harold Hill
Romford
Essex
RM3 8UG
United Kingdom

Manufacturer

Macarthy's Laboratory Limited T/A Martindale Pharma
Bampton Road
Harold Hill
Romford
Essex
RM3 8UG
United Kingdom

Marketing Authorisation Number

PL 01883/0342

This leaflet was approved:

July 2020

