

Package leaflet: information for the user

Sodium Bicarbonate 84 mg/ml Oral Solution

Sodium Bicarbonate 1 mmol/ml

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 symptoms 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.

What is in this leaflet

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

1. WHAT SODIUM BICARBONATE ORAL SOLUTION IS AND WHAT IT IS USED FOR

Sodium Bicarbonate 84 mg/ml oral solution (called Sodium Bicarbonate oral solution in this leaflet) contains the active substance sodium hydrogen carbonate which belongs to a group of medicines called antacids.

Sodium Bicarbonate oral solution is used for:

- the short-term symptomatic treatment of indigestion (dyspepsia)
- the treatment of metabolic acidosis (a condition where the body fluids and tissues are unusually acidic).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SODIUM BICARBONATE ORAL SOLUTION

Do not take Sodium Bicarbonate oral solution:

- if you are allergic to sodium bicarbonate or any of the other ingredients of this medicine (listed in section 6)
- if you have a condition where the body fluids and tissues are unusually alkaline (metabolic or respiratory alkalosis)
- if you have low levels of calcium in the blood
- if you have reduced stomach acid.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sodium Bicarbonate oral solution if you:

- have scarring of the liver caused by long-term liver damage (cirrhosis)
- are on a low sodium (salt) diet
- have heart failure, liver problems, kidney problems or high blood pressure
- have high blood pressure during pregnancy
- have a condition in which there is excessive secretion of aldosterone or other conditions associated with sodium retention
- are elderly (aged from 65 years)
- are aged under 18 years.

Please talk to your doctor if your symptoms remain the same after taking this medicine. This medicine may mask the symptoms of other illnesses such as stomach cancer or stomach ulcers.

Children and adolescents

Do not give this medicine to children under the age of 18 years because the efficacy of sodium bicarbonate has not been established.

Other medicines and Sodium Bicarbonate oral solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

- antibiotics or antifungals (to treat an infection) e.g. rifampicin, ketoconazole, tetracyclines
- phenothiazines (to treat anxiety or depression)
- corticosteroids (to treat swelling or inflammation or for allergic reactions)
- lithium (for mental illness)
- aspirin
- methotrexate (for certain types of tumours, psoriasis or rheumatoid arthritis)
- quinidine (to treat heart rhythm disorders)
- ephedrine (to treat breathing problems)
- phenytoin (for epilepsy)
- chloroquine (to prevent or treat malaria)
- penicillamine (for rheumatism)
- dipyridamole (to prevent blood clots associated with heart problems).

Sodium Bicarbonate oral solution with food, drink and alcohol

You can take Sodium Bicarbonate oral solution before or after food as directed by your doctor or pharmacist.

Pregnancy and breast-feeding

Sodium Bicarbonate oral solution should not be taken during pregnancy and breast-feeding unless advised by a doctor to do so.

Driving and using machines

Sodium Bicarbonate oral solution does not affect the ability to drive or operate machinery. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. HOW TO TAKE SODIUM BICARBONATE ORAL SOLUTION

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

Adults including the elderly

Dyspepsia: The usual dose is between 12–60 mL (approximately 1–5 g) every 4–6 hours.

Acidosis: Your doctor will calculate the recommended dose for you.

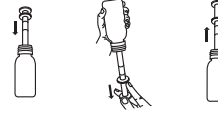
If you are elderly, you should consult your doctor before taking this medicine, and must be particularly careful to follow your doctor's instructions.

Children

Not recommended for use in children under 18 years of age.

Using the dosing syringe

1. When you use the medicine for the first time, place the adaptor in the neck of the bottle.
2. Push the syringe firmly into the adaptor in the neck of the bottle.
3. To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. Your doctor will tell you the right dose to take.
4. Turn the bottle the right way up, remove the syringe from the bottle plug by gently twisting the syringe.



5. Place the end of the syringe into your mouth and gently press the plunger down to slowly and gently release the medicine.
6. Repeat steps 2-5 as necessary to take the full dose.
7. After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.

If you take more Sodium Bicarbonate oral solution than you should

- If you take more Sodium Bicarbonate oral solution than your doctor has prescribed, or you think a child has accidentally swallowed any, contact the nearest hospital casualty department or doctor for advice.
- Take this leaflet with you.

If you forget to take Sodium Bicarbonate oral solution

If you forget a dose, take the next dose as soon as you remember. Do not take a double 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. Children are at higher risk of the effects.

Tell your doctor straightaway if you notice any of the following side effects:

- an increase in pH of the blood (alkalosis), symptoms may include tiredness/weariness, vomiting, thirst and restlessness. (Possibly due to prolonged use, which is not advised)
- fluid retention or fluid on the lungs
- worsening of an already low level of potassium in your blood (hypokalaemia)
- loss of appetite
- mood or mental changes
- nervousness or restlessness
- headache
- high blood pressure
- slow breathing or difficulty breathing
- swelling and/or fluid in the lungs (pulmonary oedema)
- stomach pain or sudden severe stomach pain that gets steadily worse (spontaneous stomach rupture)
- flatulence
- nausea or vomiting
- unpleasant taste
- swelling of feet or lower legs
- frequent urge to urinate
- extreme irritability
- unusual tiredness or weakness
- muscle spasms or cramps.

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 the Yellow Card Scheme Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SODIUM BICARBONATE ORAL SOLUTION

Do not refrigerate or freeze this medicinal product.

Once opened use within 7 days.

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

Do not use Sodium Bicarbonate oral solution after the expiry date which is stated on the bottle or carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the solution has become discoloured or shows any signs of deterioration or if crystals are observed in the solution. Seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sodium Bicarbonate oral solution contains

- Each 1 ml of solution contains 84 mg of the active substance, sodium bicarbonate (equivalent to 1 mmol/ml sodium bicarbonate).
- The other ingredient is purified water.

What Sodium Bicarbonate oral solution looks like and contents of the pack

Sodium Bicarbonate oral solution is a clear, colourless solution, free of visible particles. Sodium Bicarbonate oral solution is packed in 100 ml amber polyethylene terephthalate (PET) bottles. The pack comes with a 20 ml polypropylene (PP) and high density polyethylene (HDPE) oral syringe, with 1 ml graduation marks and a LDPE adaptor.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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