

Sodium Bicarbonate 8.4% w/v Solution for Injection

Sodium Bicarbonate

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

This medicine will be referred to as Sodium Bicarbonate Injection in the rest of this leaflet.

What is in this leaflet:

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

1. What Sodium Bicarbonate Injection is and what it is used for

Sodium Bicarbonate is one of a group of medicines known as alkalinising agents. It is used to correct the acid-alkaline balance in the body.

Sodium bicarbonate is used to reduce the amount of acid in the body after a heart attack in patients who have the following conditions: too much acid in their body or too much potassium in their blood.

It can also be used to treat patients who have taken too much tricyclic antidepressant medicine. Sodium Bicarbonate will only be used after other resuscitation methods have been attempted.

2. What you need to know before you are given Sodium Bicarbonate Injection

You should not be given Sodium Bicarbonate Injection if:

- you are allergic to Sodium Bicarbonate or any of the other ingredients of this medicine, (listed in section 6)
- your breathing is slower or more shallow than usual (hypoventilation)
- you have any blood abnormalities such as high levels of sodium, low levels of calcium, potassium or chloride, or your blood is less acidic than usual (your doctor will need to check this)
- you have had kidney stones
- you have high blood pressure
- you have kidney failure
- you have heart failure
- you suffer from fluid retention

If any of the above apply to you or your child please tell your doctor or nurse before you are given Sodium Bicarbonate Injection.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Sodium Bicarbonate Injection. Your doctor or nurse may want to regularly check your blood acid levels during the course of treatment with this medicine.

Other medicines and Sodium Bicarbonate Injection

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

- Including:
- corticosteroids or corticotropin (medicines used to reduce swelling or to treat hormone problems)
 - medicines used to treat infections (tetracyclines) such as doxycycline
 - quinidine, flecainide (medicines used to treat heart problems)
 - amphetamines (medicines used to treat certain mental disorders and drowsiness)
 - ephedrine and pseudoephedrine (medicines used to treat colds and asthma)
 - potassium supplements
 - medicines used to treat water retention and problems with passing urine such as ethacrynic acid, bumetanide, thiazides or frusemide
 - medicines used to treat high blood pressure (e.g. mecamylamine)
 - medicines used to treat Alzheimer's disease (e.g. memantine)
 - medicines used to treat diabetes mellitus (e.g. chlorpropamide)
 - medicines used to treat mood disorders (e.g. lithium)
 - Aspirin (Acetylsalicylic acid)

Pregnancy, breast-feeding and fertility

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 Bicarbonate Injection contains sodium.

This medicinal product contains 23.00 mg sodium per ml, equivalent to 1.15% of the WHO recommended maximum daily intake of 2g sodium for an adult.

Driving and using machines

This medicine is unlikely to affect your ability to drive or use machines.

3. How Sodium Bicarbonate Injection is given

Your doctor will give you Sodium Bicarbonate Injection by slow injection into the vein (intravenous injection).

Your doctor will decide on how much Sodium Bicarbonate Injection you should be given.

Adults and the elderly

- The usual starting dose is 1mmol for every kg you weigh
- Followed by 0.5 mmol/kg given at 10minute intervals

Children

- The usual dose is 1 mmol for every kg you weigh given by slow IV injection
- The medicine should be diluted 1:1 with 5% dextrose for premature infants and new-borns.

If you think you have been given too much Sodium Bicarbonate Injection

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. Your doctor has information on how to recognise and treat an overdose. If you are concerned about your treatment please talk to your doctor.

Signs of too much sodium bicarbonate include hyperventilation (over breathing), very sensitive to slight stimuli, twitching and high potassium levels in your blood which may cause you to feel dizzy or tired.

4. Possible side effects

Like all medicines, Sodium Bicarbonate Injection can cause side effects, although not everybody gets them.

Side effects include:

- Low levels of potassium causing twitching, muscle weakness, 'pins and needles' in the hands or feet, irritability or abnormal heart rhythm
- Low levels of blood sugar and high concentration of sodium in the blood causing feeling hungry, thirsty, nervous, confused, extreme irritation, increased urination, shakiness or sweating
- Too much acid in the blood, which many cause an increased rate of breathing (intracellular acidosis)
- a blood disorder consisting of an increase in the volume of circulating blood
- Low levels of calcium causing involuntary contraction of your muscles
- Swelling due to a build-up of fluid under the skin
- New born babies may have bleeding inside the skull
- Sodium bicarbonate may leak out of the veins into the surrounding tissue. This may cause pain, redness or irritation to the skin
- If the medicine is not correctly injected it could cause the skin to die around the injection site.

Reporting of side effects

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. You can also report side effects directly via Yellow Card Scheme. Website: 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 Injection

Keep all medicines out of the sight and reach of children.

This Sodium Bicarbonate Injection should not be used after the expiry date which is stated on the carton and ampoule label. 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. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. This product should only be used in a hospital environment and will be safely disposed of by your doctor.

6. Contents of the pack and other information

What Sodium Bicarbonate Injection contains

The active substance is Sodium Bicarbonate 8.4%w/v
The other ingredients are disodium edetate, nitrogen and water for injections.

What Sodium Bicarbonate Injection looks like and contents of the pack

Sodium Bicarbonate Injection is a clear, colourless solution supplied in 5ml and 10ml glass ampoules. Each pack contains 10 ampoules.

Marketing Authorisation Holder and Manufacturer

Martindale Pharma, Bampton Road, Harold Hill, Romford Essex, RM3 8UG, England

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

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Martindale
Pharma 

Bampton Road, Harold Hill, Romford, RM3 8UG, United Kingdom