TorbayPharmaceuticals

Package leaflet: Information for the patient
Sodium Bicarbonate 8.4% w/v Solution for Injection
sodium bicarbonate

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.**
- **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.**

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

The name of your medicine is Sodium Bicarbonate 8.4% w/v Solution for Injection. This will be referred to as Sodium Bicarbonate Injection throughout this leaflet.

Sodium bicarbonate is a simple chemical which is used in medicine when your blood contains too much acid.

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 Injection 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 will be given Sodium Bicarbonate Injection in hospital by a doctor or nurse.

Do not use 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 high blood pressure
- you have kidney failure
- you have heart failure
- you suffer from fluid retention

If any of the above apply to you 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.

Talk to your doctor if you are taking:

- corticosteroids or corticotropin (medicines used to reduce swelling or to treat hormone problems)
- medicines of an acidic nature (e.g. tetracycline, doxycycline or methenamine)
- 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 Alzheimers 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 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 Bicarbonate Injection will only be given to you if your doctor considers the treatment necessary.

Driving and using machines

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

Sodium Bicarbonate Injection contains sodium

This medicine contains 23 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 1.15% of the recommended maximum daily dietary intake of sodium for an adult.

The following information is intended for healthcare professionals only:

Therapeutic indications

Sodium Bicarbonate Injection is indicated in adults and children for:

- Correction of metabolic acidosis associated with cardiac arrest in patients with pre-existing metabolic acidosis
- Cardiac arrest associated with hyperkalaemia with pre-existing metabolic acidosis
- Life threatening hyperkalaemia with pre-existing metabolic acidosis
- Tricyclic antidepressant overdose

Sodium bicarbonate should only be used after other resuscitative measures such as cardiac compression, ventilation, adrenaline and antiarrhythmic agents have been attempted.

In neonates, Sodium Bicarbonate Injection is indicated for:

- Correction of metabolic acidosis associated with cardiac arrest in patients with pre-existing metabolic acidosis
- Cardiac arrest associated with hyperkalaemia with pre-existing metabolic acidosis
- Life threatening hyperkalaemia with pre-existing metabolic acidosis

No benefits have been demonstrated from the routine use of sodium bicarbonate in resuscitation of neonates. In neonates, sodium bicarbonate is recommended in resuscitation only in cases of prolonged cardiac arrest, irresponsive to other therapy, after establishment of adequate ventilation and circulation.

Posology and method of administration

Posology

The posology depends largely on the extent of the acid-base imbalance. This should be checked regularly.

Adults:
The usual dose is 1 mmol/kg (1 mL/kg 8.4% solution) followed by 0.5 mmol/kg (0.5 mL/kg 8.4% solution) given at 10-minute intervals.

Paediatric population:
The usual dose is 1 mmol/kg by slow iv injection (1 mL/kg 8.4% solution)

In premature infants and neonates, the 8.4% solution should be diluted 1:1 with 5% w/v dextrose.

Elderly:

As for adults.

Method of administration

For intravenous administration only.

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 1 mmol for every kg you weigh
- Followed by 0.5 mmol/kg given at 10-minute intervals

Children

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

If you think you have been given more Sodium Bicarbonate Injection than you should

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, if you think you have been given too much of this medicine, please tell your doctor.

Signs of too much sodium bicarbonate include hyperventilation (over-breathing), sensitivity 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, this medicine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme 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 Injection

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 the ampoule label. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice it has visible particles.

Discard container and any unused content after use.

Do not throw away any medicines 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. Each 1 mL solution for injection contains 84 mg sodium bicarbonate.
- The other ingredients are disodium edetate and Water for Injections.

What Sodium Bicarbonate Injection looks like and contents of the pack

Sodium Bicarbonate Injection is a clear and colourless aqueous solution supplied in 10 mL glass ampoules. Each pack contains 10 ampoules.

Marketing Authorisation Holder and Manufacturer

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Incompatibilities

The addition of sodium bicarbonate to parenteral solutions containing calcium should be avoided except where compatibility has been previously established; precipitation or haze may result, should this occur, the solution should not be used.

Administration of sodium bicarbonate is incompatible with allopurinol sodium, amiodarone hydrochloride, anileridine, ascorbic acid injection, carmustine, cefamandole, cefotaxime, codeine phosphate, dobutamine hydrochloride, dopamine hydrochloride, doxapram, epinephrine hydrochloride, esmolol, fenoldopam mesylate, glycopyrrolate, hydromorphone hydrochloride, idarubicin hydrochloride, inamrinone lactate, isoproterenol hydrochloride, labetalol hydrochloride, levofloxacin, levophanon tatrate, magnesium sulfate, methadone, metoclopramide hydrochloride, morphine sulfate, moxalactam, nicardipine hydrochloride, norepinephrine bitartrate, ondasetron hydrochloride, oxytetracycline, pentazocine lactate, sargramostin, secobarbital, streptomycin sulfate, succinylcholine chloride, tetracycline, ticarcillin disodium/clavulanate potassium, trimethaphan, tubocurarine and vinorelbine tartrate.

It is also incompatible with the solutions of: alcohol 5% in dextrose 5%, dextrose 5% in lactated Ringer's injection, ionosol(R) B in invert sugar 10%, ionosol(R) D, modified in invert sugar 10%, isonosol(R) D in invert sugar 10%, and ionosol(R) G in invert sugar 10%.