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PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Medical Limited · Dublin 12, Ireland

8.4% w/v Sodium Bicarbonate Intravenous Infusion BP

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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP is and what it is used for
2. What you need to know before you receive 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP
3. How to use 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP
4. Possible side effects
5. How to store 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP
6. Contents of the pack and other information

1. WHAT 8.4 % W/V SODIUM BICARBONATE INTRAVENOUS INFUSION BP IS AND WHAT IT IS USED FOR

This medicine contains sodium bicarbonate (bicarbonate of soda), a substance that is able to neutralise acidic substances.

8.4% w/v Sodium Bicarbonate Intravenous Infusion BP is used:

- to neutralise excess acidic (= sour) substances in the blood
- to render the urine more basic (or alkaline) in the case of poisoning with acidic substances, e.g. phenobarbital or acetylsalicylic acid, in order to accelerate their excretion
- to render the urine more basic (or alkaline) in order to make some drug substances, e.g. methotrexate, sulfadiazine, more soluble to improve their excretion in urine to render the urine more basic (or alkaline) in order to prevent blocking of the kidneys by haemoglobin fragments in the case of a massive breakdown of red blood cells (haemolysis).

2. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE 8.4 % W/V SODIUM BICARBONATE INTRAVENOUS INFUSION BP**You should not receive 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP**

- if you are allergic to sodium bicarbonate or any of the other ingredients of this medicine (listed in section 6)
- if your blood is already too alkaline
- if your breath is slow or shallow or both
- if your blood sodium level is abnormally high
- if your blood potassium level is abnormally low
- if you lose too much chloride

Warnings and precautions

Talk to your doctor before using 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP

Your doctor will take special care

- if your blood is too acidic because of breathing problems or lung problems
- if your blood calcium level is abnormally low

- if your blood has in total an abnormally high concentration of salts (hyperosmolarity)
- if you have any disease or condition where your sodium intake should be low, e.g. heart failure, fluid retention associated with swelling, high blood pressure, eclampsia (a condition associated with tissue swelling and convulsions during pregnancy) or kidney failure

If breathing problems or lung problems are part of the reason why your blood is too acidic, care will be taken to help you breathe properly to get rid of the excess CO₂ that is produced after administration of this medicine.

Administration of this medicine may lead to sodium and fluid overload. Care will be taken to control your blood electrolyte levels, in particular potassium. Your fluid and acid-base balance will also be monitored.

If necessary you will receive potassium and calcium supplements before you receive this medicine.

It will be made sure that the cannula or small tube is correctly placed in a vein in order to avoid severe complications.

The effects of sodium bicarbonate in some conditions leading to too much acidic substances in your blood, namely diabetic ketoacidosis, cardiac arrest or lactic acidosis, have not been investigated completely. If you suffer from these conditions, special care will be taken.

Children

Special care will be taken in newborn infants, infants and toddlers, since a too rapid infusion of sodium bicarbonate solutions may lead to too much sodium in the blood, a decrease in the pressure of the brain fluid and (in preterm newborn infants) bleeding within the skull.

Other medicines and 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP

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

Sodium bicarbonate may interact with other medicines, in particular

- corticosteroids, e.g. hydrocortisone, prednisone
- male sex hormones (androgens)
- medicines increasing the urine flow (diuretics) in particular those that promote potassium excretion.

Sodium bicarbonate promotes the excretion of acidic drug substances, e.g. acetylsalicylic acid, which may lead to a shortening or weakening of their effects. It may also delay the excretion of alkaline drug substances, which may make their effects longer lasting or stronger.

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 for advice before taking this medicine.

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Pregnancy

If you are pregnant, you will receive this medicine only if your doctor considers it absolutely necessary for your recovery. Your doctor will exercise caution when administering this medicine to you if you suffer from toxæmia of pregnancy, because the high sodium content of this medicine might be dangerous for you.

Breast-feeding

If you are breast-feeding, you will receive this medicine only if your doctor thinks that the benefits clearly outweigh the risks.

Driving and using machines

This medicine has no influence on the ability to drive and use machines.

3. HOW TO USE 8.4 % W/V SODIUM BICARBONATE INTRAVENOUS INFUSION BP

This medicine will be given to you by a doctor or a nurse. You will be given this medicine by a drip via a small tube or cannula placed in a large vein. Your doctor will calculate the right dose of this medicine for you. He/she will also decide for how long the infusion should be given. This will depend on your clinical condition.

For urine alkalinisation your dose is adjusted according to the desired degree of alkalinity and administration will be accompanied by careful monitoring of the acid-base balance, the water balance and the blood salt concentrations.

If you received more 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP than you should

Overdose may render your blood too alkaline or lead to an abnormally high blood sodium level or abnormally high salt levels in your blood. It may also lead to fluid excess. Too rapid infusion may be associated with an increased risk of brain damage resulting from an increased carbon dioxide load, especially when you have breathing problems.

Treatment

Your doctor will decide on further treatment and medication that you may need.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The possible side effects are listed according to their frequency.

Not known (frequency cannot be estimated from the available data):

- Abnormally high blood sodium level, abnormally high blood salt levels.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE 8.4 % W/V SODIUM BICARBONATE INTRAVENOUS INFUSION BP

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

To avoid formation of crystals, do not refrigerate or freeze. Do not store above 25 °C.

Do not use this medicine after the expiry date which is stated on the bottle and the outer carton. The expiry date refers to the last day of that month.

This medicine is an almost saturated solution and should therefore not be stored below normal room temperature. Crystals which may possibly have developed during storage can be dissolved by simply warming the bottle. Once opened this product should be used immediately.

Do not use this medicine if you notice

- cloudiness of the solution
- particles in the solution
- discolouration of the solution
- leaking of the bottle.

Containers are for single use only. After use discard bottle and any unused content.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP contains**

- The active substance is Sodium Hydrogen Carbonate (Sodium bicarbonate).

100 ml of the solution contains 8.4 g of Sodium Hydrogen Carbonate (Sodium bicarbonate).

- The other ingredients are disodium edetate and water for injections.

What 8.4% w/v Sodium Bicarbonate Intravenous Infusion BP looks like and contents of the pack

8.4% w/v Sodium Bicarbonate Intravenous Infusion BP is a solution for infusion (administration as a vein drip).

It is a clear, colourless, sterile solution of sodium bicarbonate in water.

Theoretical osmolality 2000 mOsm/l
pH 7.0-8.5

- It comes in colourless glass bottles sealed with rubber stoppers containing 100 ml supplied in packs of 20 x 100 ml

Marketing Authorisation Holder and Manufacturer**PA Holder**

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PA Number

PA 179/6/1

Manufacturer

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This leaflet was last approved in 04/2016.

The following information is intended for healthcare professionals only:

- Discontinue if adverse reaction occurs.

- No other medication or substance should be added unless compatibility is known.

- For use only with a giving set containing an integral airway.

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