SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Bicarbonate 8.4% solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Bicarbonate 8.4% w/v

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of metabolic acidosis and rapid urine alkalinisation.

4.2 Posology and method of administration

Posology

Adults and Children

The volume, strength and rate of infusion will depend upon the requirements of the individual patients as perceived by the physician. Administration should be effected cautiously and gradually. In the less urgent forms of metabolic acidosis, an average dose for adults and older children is 2 – 5 mmol of bicarbonate per Kg bodyweight, given over 4 - 8 hours. Subsequent doses of sodium bicarbonate should be adjusted to the individual patients' requirements. It is generally recommended that administration should be initiated with half the calculated dose, which may be adjusted subject to satisfactory blood gas analysis.

Elderly

Care should be taken to avoid circulatory overload, particularly in, patients with cardiac and renal insufficiency.

Method of administration

For intravenous infusion.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Intravenous infusions of sodium bicarbonate may be contraindicated in, patients with hypertension, impaired renal and cardiac function, pulmonary oedema, respiratory and metabolic alkalosis, hyperventilation, hypernatraemia and eclampsia.

4.4 Special warnings and precautions for use

Infusion of sodium bicarbonate solutions must be strictly intravenous, since extravasation may lead to tissue necrosis. Administration to patients receiving cardio-pulmonary resuscitation may induce pulmonary oedema.

Careful attention should be given to avoid possible hypokalaemia.

The label states: Do not use unless solution is clear and free from particles.

4.5 Interaction with other medicinal products and other forms of interaction

Sodium bicarbonate will alkalinise the urine and reduce the urinary excretion of amphetamines, methadone, quinidine and quinine. Sodium bicarbonate will reduce the effectiveness of hexamine compounds, which are only effective as urinary antiseptics in acid urine. The renal excretion of lithium appears to be increased by sodium bicarbonate and this could lead to reduced plasma levels of lithium and impairment of the therapeutic response.

4.6 Fertility, pregnancy and lactation

The safety of sodium bicarbonate infusion during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Thrombosis of the chosen vein is always a possibility with intravenous infusion.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

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4.9 Overdose

Overdoses may cause hyperpnoea, nausea and convulsions. Particular care should be paid to administration in the elderly and infants. Over-rapid infusion may lead to hyperosmolarity. In cases of overdosage the infusion of sodium bicarbonate should be discontinued immediately and metabolic alkalosis corrected by means of administration of 0.9% wlv sodium chloride intravenous infusion BP.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium bicarbonate provides a source of bicarbonate ions, which will neutralise the relative excess of hydrogen ions present in acidotic conditions.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections

Disodium Edetate

Carbon Dioxide

6.2 Incompatibilities

A number of drugs are incompatible with sodium bicarbonate infusions including:

Ascorbic acid, adrenaline, benzyl penicillin, calcium chloride, calcium gluconate, calcium salts of drugs, carmustine, cisplatin, codeine phosphate, corticotrophin, dobutamine, insulin, labetalol, levorphanol, magnesium salts, methadone, morphine sulphate, noradrenaline, oxytetracycline, pethidine, pentobarbitone, procaine, streptomycin, suxamethonium, tetracycline, vancomycin and vitamin B complex with C.

6.3 Shelf life

12 months

6.4 Special precautions for storage

Store between 10° - 25°C

6.5 Nature and contents of container

Sealed semi-rigid, cylindrical neutral polythene container with a 'Twist-off' seal at one end and a ring tab at the opposite end.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Do not dilute before use.

Use standard sterile peritoneal dialysis equipment.

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
Cestrian Court
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Manor Park
Runcorn
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WA7 1NT

8 MARKETING AUTHORISATION NUMBER

PL 08828/0043.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation – Apr 1989

Date of renewal of authorisation – 20 Jan 2009

10 DATE OF REVISION OF THE TEXT

19/04/2024