Summary of Product Characteristics for Pharmaceutical Products

1 Name of the medicinal product

NatBic (Sodium Bicarbonate 8.4%)Solution for Injection

2 Qualitative and quantitative composition

Each 1ml solution for injection contains 84mg Sodium bicarbonate equivalent to 23mg (1mEq) of Sodium and 61mg (1mEq) of Bicarbonate

For the full list of excipients, see section 6.1.

3 Pharmaceutical form

Solution for injection
Clear Colorless Solution

4 Clinical particulars

4.1 Therapeutic indications

- 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 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.

4.2 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 1mmol/kg (1ml/kg 8.4% solution) followed by 0.5mmol/kg (0.5ml/kg 8.4% solution) given at 10-minute intervals.

Paediatric population:
The usual dose is 1mmol/kg by slow iv injection. (1ml/kg 8.4% solution)
In premature infants and neonates, the 8.4% solution should be diluted 1:1 with 5% dextrose.

Elderly:
As for adults.

Method of administration
For intravenous administration only.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Conditions where sodium intake is restricted (e.g., renal failure, hypertension, oedema, congestive heart failure)
- Patients with hypoventilation (risk of worsening of acidosis)
- Metabolic or respiratory alkalosis
- Patients with a history of urinary calculi
- Patients with coexistent potassium depletion or chloride depletion, hypocalcaemia and hypernatremia.

4.4 Special warnings and precautions for use

Whenever sodium bicarbonate is used intravenously, arterial blood gas analyses, in particular arterial/venous blood pH and carbon dioxide levels, should be performed before and during the course of treatment to minimise the possibility of overdosage and resultant alkalosis.

Accidental extravascular injection of hypertonic solutions may cause vascular irritation or sloughing. The use of scalp veins should be avoided.

Whenever respiratory acidosis is concomitant with metabolic acidosis, both pulmonary ventilation and perfusion must be adequately supported to get rid of excess CO_2.

Administration of sodium bicarbonate to a patient with inadequate minute ventilation can cause worsening of the acidosis.

The treatment of metabolic acidosis must, if possible, be combined with concurrent treatment to combat the primary cause of the acidosis, for example the administration of insulin in uncomplicated diabetes, or blood volume restoration in shock.

In long-term therapy, care is essential to prevent the risk of overdose and alkalosis. Therefore, repeat administrations of fractional doses, or an infusion, should be given while regularly monitoring the acid-base balance and electrolytes. As soon as the most severe symptoms are under control, the dose and frequency of administration must be reduced until normal values have been restored.
There is no evidence to support the use of bicarbonate therapy in the treatment of hypoperfusion-induced lactic academia associated with sepsis.

Sodium Bicarbonate 8.4% w/v Solution for Injection contains sodium
This medicinal product contains 23mg sodium per ml, equivalent to 1.15% of the WHO recommended maximum daily intake of 2g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

Caution should be used when administering sodium ions to patients receiving corticosteroids or corticotrophin.

Urinary alkalisation will increase the renal clearance of medicinal products which are acid in nature e.g., tetracyclines, especially doxycycline, acetylsalicylic acid, chlorpropamide, lithium, methenamine. It increases the half-life and duration of action of basic drugs such as quinidine, amphetamines, ephedrine, pseudoephedrine, memantine and flecainide. Sodium bicarbonate is known to increase renal tubular reabsorption of mecamylamine causing hypotension.

Hypochloraemic alkalosis may occur if sodium bicarbonate is used in conjunction with potassium depleting diuretics such as bumetamide, ethacrynic acid, frusemide and thiazides.

Concurrent use in patients taking potassium supplements may reduce serum potassium concentration by promoting an intracellular ion shift.

4.6 Fertility, pregnancy and lactation

Safe use in pregnancy has not been established. The use of any drug in pregnant or lactating women requires that the expected benefit be carefully weighed against the possible risk to the mother and child.

Patients requiring IV sodium bicarbonate are unlikely to be fit enough to breast feed.

4.7 Effects on ability to drive and use machines

Not applicable; this preparation is intended for use only in emergencies.

4.8 Undesirable effects

Tabulated summary of adverse reactions

Adverse events are listed below by system organ class and frequency. The following adverse reactions have been reported in post-marketing experience.

Term	Frequency of occurrence
Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1 000 to <1/100)
Rare	(≥1/10 000 to <1/1 000)
Very rare	(<1/10 000)
Not known	(Cannot be estimated from the available data)

System Organ Class	Frequency	Undesirable effects
Metabolism and nutrition disorders	Not Known	Alkalosis, hypokalaemia, hypernatremia, hyperosmolarity, hypocalcaemia, hypoglycaemia, paradoxical intracellular acidosis
Cardiac disorder	Not Known	Deterioration of hemodynamic status associated with volume overload

Nervous system disorders	Not Known	Intracranial haemorrhage (in neonates), hyperirritability or tetany
General disorders and administration site conditions	Not Known	Extravasation. Incorrect administration (intra-arterial, paravenous) may cause tissue necrosis

4.9 Overdose

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

Symptoms: metabolic alkalosis accompanied by compensatory hyperventilation, paradoxical acidosis of the cerebrospinal fluid, severe hypokalaemia, hyperirritability and tetany.

Treatment: discontinue the administration of sodium bicarbonate, rebreathe expired air or, if more severe administer calcium gluconate especially if tetany is present. In severe alkalosis, an infusion of 2.14% ammonium chloride is recommended, except in patients with pre-existing hepatic disease. If hypokalaemia is present administer potassium chloride.

5 Pharmacological properties

5.1 Pharmacodynamic properties

ATC Code: B05XA02

Sodium bicarbonate therapy increases plasma bicarbonate, buffers excess hydrogen ion concentration, raises blood pH and reverses clinical manifestations of metabolic acidosis.

5.2 Pharmacokinetic properties

Sodium bicarbonate is eliminated principally in the urine and effectively alkalises it.

5.3 Preclinical safety data

Not applicable since sodium bicarbonate has been used in clinical practice for many years and its effects in man are well known.

6 Pharmaceutical particulars

6.1 List of excipients

Disodium Edetate
Sodium hydroxide
Water for Injections.

6.2 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%

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Type 1 glass ampoules 10ml containing a 8.4% w/v sterile solution for injection of Sodium Bicarbonate. Packed in cartons of 10 ampoules.

6.6 Special precautions for disposal and other handling

None stated.

7. Marketing authorization holder and manufacturing site addresses

Marketing authorization holder:
Tasa Pharma Ltd
Address: Unit C1-C3, Kay Complex, Mombasa Road, Nairobi, P.O. Box 3959-00506
Country: Kenya

Manufacturing site address:
Tasa Pharma Ltd
Address: Unit C1-C3, Kay Complex, Mombasa Road, Nairobi, P.O. Box 3959-00506
Country: Kenya

8. Marketing authorization number

CTD9906

9. Date of first registration

28/03/2023

10. **Date of revision of the text:**

18/09/2023

11. **Dosimetry:**

Not Applicable

12. **Instructions for Preparation of Radiopharmaceuticals:**
Not Applicable