SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE CONTAINING SOLUTION FOR INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

One ampoule contains 0.84 g sodium bicarbonate.

Excipients:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sterile, clear, colorless and particle-free aqueous solution for parenteral administration.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

It is indicated for the correction of metabolic acidosis due to cardiac arrest, following reconstructive measures such as cardiac compression, ventilation and the use of adrenaline and antiarrhythmic agents.

4.2. Posology and method of administration

Posology /administration frequency and duration

Adult dose: Common dose is 1 mmol/kg (1 mL/kg) followed by 0.5 mmol/kg at 10 minute intervals. (0.5 mL/kg).

Method of administration:

For intravenous administration only.

Additional information on special populations:

Renal failure:

It should not be used in patients with renal failure.

Hepatic failure:

There is no study on hepatic failure.

Pediatric population:

Child dose: the common dose is 1 mmol/kg with slow intravenous injection.

In premature infants and newborns, solutions of 4.2% can be used, or solution of 8.4% can be diluted with a solution of 5% dextrose in a 1:1 ratio.

Geriatric population:

Adult dose use is appropriate in geriatric patients; no special dose adjustment is required.

4.3. Contraindications

The use of MOLAR SODIUM BICARBONATE is contraindicated in the following cases:

- Renal failure
- Metabolic or respiratory alkalosis
- Hypertension
- Edema
- Congestive heart failure
- A history of kidney stones accompanied by potassium deficiency or hypocalcemia
- Hypoventilation
- Chlorine deficiency or lipernatremia

4.4. Special warnings and special precautions for use

When sodium bicarbonate is used intravenously, arterial blood analysis, especially arterial / venous blood pH and carbon dioxide level analysis should be performed during and before treatment to minimize the resulting alkalosis and overdose.

Accidental injection of hypertonic solutions out of a vein can cause vascular irritation or rash. Administration to scalp veins should be avoided.

If respiratory acidosis is associated with metabolic acidosis, adequate pulmonary ventilation and perfusion should be performed to remove excess CO_2.

This medicinal product contains 230 mg of sodium in each ampoule. This condition should be considered for patients on a controlled sodium diet.

Because this preparation contains intense salt, particles can form. Preparations containing particles should not be used.

4.5 Interaction with other medicinal products and other forms of interaction

Care should be taken when sodium ions are administered to patients receiving corticosteroids and corticotropins.

Urine alkalization increases the renal clearance of tetracyclines, especially doxycycline; it increases the duration and half-life of basic drugs such as quinidine, amphetamine, ephedrine and pseudoephedrine.

Hypochloremic alkalosis can occur when sodium bicarbonate is used in combination with diuretics that reduce the level of potassium, such as bumetamide, etacrinic acid, furosemide, and thiazides.

In patients taking potassium-supporting products simultaneously, serum potassium levels may decrease with intracellular ion exchange.

4.6 Pregnancy and lactation

General advice

Pregnancy category: C

Women with childbearing potential / Contraception

There is not enough data on the use of sodium bicarbonate in pregnant women.

Pregnancy

The safety of sodium bicarbonate in pregnant women has not been determined. Sodium bicarbonate should not be used in pregnant women unless the benefit it will provide to the mother exceeds the risk of harm it may cause to the fetus.

Lactation

It is not suitable for patients receiving intravenous sodium bicarbonate to breastfeed their babies.

Fertility

Its effect on reproductive ability has not been investigated.

4.7 Effects on ability to drive and use machines

As this preparation is intended for use only in emergency situations, it cannot be applied

4.8 Undesirable effects

Alkalosis and/or hypokalemia develop as a result of long-term or high-dose use of sodium bicarbonate to correct bicarbonate deficiency.

Hyperiritability or tetany occurs due to serum protein level changes caused by rapid transition of free ionized calcium or pH change.

4.9 Overdose and treatment

Symptoms:

Compensatory hyperventilation to metabolic alkalosis, paradoxic acidosis of cerebrospinal fluid, severe hypokalemia, hyperirritability and tetany.

Treatment:

In case of overdose, sodium bicarbonate treatment is terminated, inhaled air is inhaled again, or calcium gluconate is administered if severe, especially if tetany has formed. In case of the occurrence of severe alkalosis, an infusion of 2.14% of ammonium chloride is recommended, except for patients with liver disease.

In case of hypokalemia, potassium chloride is administered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Blood Substitutes and Perfusion Solutions

ATC code: B05XA02

Sodium bicarbonate increases plasma bicarbonate levels, buffers excess hydrogen ions, increases blood pH, and eliminates clinical signs of metabolic acidosis.

5.2 Pharmacokinetic properties

Sodium bicarbonate is excreted mainly in the urine and effectively alkalizes the urine.

5.3 Preclinical safety data

Because sodium bicarbonate has been used in the clinic for many years and all its effects in humans are well known, it is not applied.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection

6.2 Incompatibilities

Precipitation or turbidity may occur by adding sodium bicarbonate to parenteral solutions containing calcium other than parenteral solutions that have already been proven to be compatible; in this case, the precipitated or blurred solution should not be used.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at room temperature below 25°C.

6.5 Nature and contents of container

10 mL ampoules containing 8.4% sodium bicarbonate, in boxes of 10 and 100 ampoules.

6.6 Special precautions for disposal

Unused products or waste materials must be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

7. MARKETING AUTHORISATION HOLDER

Name **:** Osel İlaç San. ve Tic. AŞ.

Address **:** Akbaba Mah. Maraş Cad. No.:52

34820 Beykoz/ İstanbul/TURKEY

Phone **:** 0216 320 45 50 (Pbx)

Fax **:** 0216 320 41 45

E-mail **:** osel@osel.com.tr

8. MARKETING AUTHORISATION NUMBER

192/80

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10. DATE OF REVISION OF THE TEXT