PATIENT INFORMATION LEAFLET

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

Administered only by intravenously.

- ***Active Ingredient:*** Contains 0.84 g sodium bicarbonate in each 10 mL ampoule
- ***Excipients:*** Water for injection

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 pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use high or low doses other than the recommended dosage.*

What is in this leaflet:

1. What MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE is and what it is used for?

MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE is an ampoule containing sodium bicarbonate as its active ingredient. It is marketed in 10 mL x 10 ampoules and 10 mL x 100 ampoules containing 0.84 g sodium bicarbonate in each 10 mL.

MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE is used to return body pH to normal after cardiac arrest. During cardiac arrest, excessive amount of acid emerges in the body and the increased amount of acid is returned to normal with sodium bicarbonate injection.

2. What you need to know before you use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

DO NOT USE MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

If ;

- You have kidney failure,
- You have an acid-base imbalance in the metabolism or respiratory system (metabolic or respiratory alkalosis),
- You have high blood pressure (hypertension),
- You have a edema
- Your heart is not able to pump the blood your body needs (congestive heart failure),
- You have potassium deficiency with a history of kidney stones or low serum calcium levels,
- You have respiratory failure (hypoventilation),
- You have chlorine deficiency or have high serum sodium levels,

Use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE CAREFULLY if;

- You are pregnant
- You are breastfeeding

Use of MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE with food and drink

There is no interaction with food due to the way of use.

Pregnancy

Consult your doctor or pharmacist before using this medication.

It is not recommended to use during pregnancy unless it is a medical necessity.

If you notice that you are pregnant during treatment, consult your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before using this medication.

If this medicine is administered intravenously, do not breast-feed.

Driving and using machines

MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE has no effect on driving and using machines.

Important information about some of the excipients in MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

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

Other medicines and MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE should be used with caution with the following drugs.

- Corticosteroids and corticotropin (eg used to treat arthritis)

- Tetracyclines especially doxycycline (antibiotic)
- Quinidine (used for heart disease),
- Amphetamine,
- Ephedrine (can be found in sprays used for nasal congestion) Pseudoephedrine (for example, it can be found in drugs used in flu infections.)
- Diuretics that lower the potassium level such as bumetamide, ethacrinic acid, phyrosemide and thiazides
- Potassium supplements

Please inform your doctor or pharmacist if you are currently using any prescription or non-prescription medication or if you have recently used it.

3. How to use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

Instructions for proper use and dosage / administration frequency:

The administration dose varies depending on the amount of acid in the blood.

The common starting dose is 1 mmol per kg of body weight. This expression means that if your body weight is 50 kg, 50 x 1 = 50 mmol MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE will be applied to you.

Method of administration
For intravenous use only.

Different age groups

Use in children:

Child dose: Common dose is 1 mmol / kg by slow intravenous injection.

In premature babies and newborns; 4.2% solutions can be used or the 8.4% solution can be diluted 1: 1 with a 5% dextrose solution.

Use in the elderly:

Adult dosage is suitable for geriatric patients.

Special cases for use:

Renal failure:

It should not be used in patients with renal failure.

Liver failure:

There are no studies conducted on liver failure.

Your doctor will determine the dose of your medication and administer it to you, depending on your illness.

If you have an impression that the effect of MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE is too strong or too weak, consult to your physician or pharmacist.

If you use more MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE than you should

Consult to a physician or pharmacist if you have used more MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE than you should use.

If you forget to use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

Do not use a double dose to make up for a forgotten dose.

Side effects after concluding treatment with MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

Not valid.

4. Possible side effects

Like all medicines, MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE may have side effects in people who are sensitive to substances in its content.

If you have any of the following, stop using MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE and IMMEDIATELY tell your doctor or contact the emergency department of your nearest hospital:

- Extreme sensitivity
- Muscle contraction

These are all very serious side effects. You may need immediate medical attention or hospitalization.

If you notice any of the following, tell it to your doctor immediately or contact the emergency department of the hospital nearest you:

- Decrease in serum potassium level or serum acid-base imbalance (alkalosis)

These are all serious side effects. Emergency medical attention may be required.

Tell your doctor if you notice any of the following:

- Feeling of tightness

These are the weak side effects of MOLAR SODIUM BICARBONATE OSEL 8,4%

AMPOULE.

If you encounter any side effects not mentioned in this patient information leaflet, please inform your doctor or pharmacist.

5. How to store MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

Keep MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

If precipitation occurs, do not use it.

Use in accordance with the expiry date.

Do not use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE after the expiry date which is stated on the package.

If you notice any defects in the product and / or packaging, do not use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE

Since this preparation contains intense salt, particles may be seen, ampoules in this case should not be used.

Marketing Authorization Holder and Manufacturing Site:

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This patient information leaflet approved in ../../....

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

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8. MARKETING AUTHORISATION NUMBER

192/80

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First authorisation date: 30.06.1999

Renewal date of authorization: 11.05.2005

10. DATE OF REVISION OF THE TEXT