

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?***
- 2. What you need to know before you use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE***
- 3. How to use MOLAR SODIUM BICARBONATE OSEL 8,4% AMPOULE?***
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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, furosemide 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, $50 \times 1 = 50$ 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.

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