

 PACKAGE LEAFLET:
Information for the patient

BIKARBONAT NATRIUMI

**Solution for injection – 840 mg / 10 ml
(Sodium bicarbonate)**

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Bikarbonat natriumi is and what it is used for
2. Before you take Bikarbonat natriumi
3. How to take Bikarbonat natriumi
4. Possible side effects
5. How to store Bikarbonat natriumi
6. Further information

1. WHAT BIKARBONAT NATRIUMI IS AND WHAT IT IS USED FOR

Bikarbonat natriumi 840 mg / 10 ml is a preparation which is injected into the vein.

It is used to restore normal pH to the body after a cardiac arrest. During a cardiac arrest (stopping of the heart), a considerable amount of acid in the body can be accumulated (metabolic acidosis). As sodium bicarbonate is alkaline, it is used to neutralize this acidity.

Your doctor may have given you Bikarbonat natriumi for another reason. Ask your doctor if you want to know why you were given this drug.

2. BEFORE YOU TAKE BIKARBONAT NATRIUMI

Do not take Bikarbonat natriumi if you:

- are hypersensitive to sodium bicarbonate or to any other ingredients of the solution for injection;
- suffer from renal failure;
- suffer from hypertension;
- have oedema;
- have metabolic or respiratory alkalosis;
- suffer from chloride loss or hypernatremia;
- suffer from congestive heart failure;
- have hypocalcemia.

If you think you have any of the above conditions, do not take the drug but ask your doctor first for advice and follow his instructions.

Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken other drugs such as:

- corticosteroids and corticotropin;
- tetracycline because urine alkalisation increases renal clearance of tetracyclines, especially of doxycycline;
- quinidine, amphetamine, ephedrine and pseudoephedrine because the administration of sodium bicarbonate increases their half-life and the effect of these alkaline drugs.

Attention! By simultaneous administration of sodium bicarbonate with diuretics that reduce levels of potassium, as thiazide diuretics, furosemide, bumetanid, ethacrynic acid, hypochloremic alkalosis may occur.

Pregnancy and breast-feeding

There are no studies about the safe use of sodium bicarbonate in pregnant women.

Like for any other drug, the use of sodium bicarbonate in pregnant women or mothers who are breast-feeding requires that the benefits expected to be obtained by treatment to be well thought out and a careful balance with the potential risk to mother and child should be performed.

Sodium bicarbonate is not recommended in breast-feeding mothers.

3. HOW TO TAKE BIKARBONAT NATRIUMI

The injection of this drug is always performed by the responsible doctor or nurse.

Bikarbonat natriumi should be injected slowly into the vein, in doses depending on the pathology, on the acid-base and hydroelectrolyte balance and on the condition of the organism.

If you take more Bikarbonat natriumi than you should

An overdose from this drug should normally not occur since it is administered from the medical staff and can not be taken in home conditions.

However, in case of an overdose, the possible side effects are: metabolic alkalosis, severe hypokalemia, hyperirritability and tetany.

In case of an overdose, it is recommended to discontinue the administration of sodium bicarbonate, 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 hypokalemia is present, administer potassium chloride.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they may be serious, sometimes not.

Do not panic from this list of side effects. You may not get any of them. Inform your doctor if any of the below side effects bothers you:

- long-term use of sodium bicarbonate may cause alkalosis and / or hypokalaemia, hypernatremia, hyperosmolarity;
- hyperirritability or tetany;
- local pain and tissue necrosis because of extravasation.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE BIKARBONAT NATRIUMI

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use after the expiry date which is stated on the package.

Store in the original package to protect it from humidity!

6. FURTHER INFORMATION

What Bikarbonat natriumi contains

The active substance is sodium bicarbonate.

One ampoule 10 ml contains 840 mg sodium bicarbonate.

The other ingredients are: disodium edetate, water for injection.

Content of the pack

Box with 10 ampoules.

100 ampoules (hospital use).

Explanatory of the illustration icons on the packaging:

 Ask your doctor or pharmacist.

 Content.  Warning.

 Solution for injection - Ampoules

Marketing Authorisation Holder and Manufacturer:

 **PROFARMA Sh.a.**
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - Albania

This leaflet was last revised in March 2012.

PAY ATTENTION, all the layers are visible.

If you have to print this document please check or uncheck the specific layers.

