APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

SODIUM BICARBONATE 4 % INJECTION FRESENIUS

SODIUM BICARBONATE 8,5 % INJECTION FRESENIUS

Solution for injection

Sodium bicarbonate

Sugar free.

Read all of this leaflet carefully before you are given SODIUM BICARBONATE INJECTION FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What SODIUM BICARBONATE INJECTION FRESENIUS is and what it is used for
2. What you need to know before you are given SODIUM BICARBONATE INJECTION FRESENIUS
3. How to receive SODIUM BICARBONATE INJECTION FRESENIUS
4. Possible side effects
5. How to store SODIUM BICARBONATE INJECTION FRESENIUS
6. Contents of the pack and other information

1. What SODIUM BICARBONATE INJECTION FRESENIUS is and what it is used for

SODIUM BICARBONATE INJECTION FRESENIUS belongs to a group of medicines called electrolyte solutions. It is used to correct the acid-base balance in the body.

2. What you need to know before you are given SODIUM BICARBONATE INJECTION FRESENIUS

SODIUM BICARBONATE INJECTION FRESENIUS should not be given to you:

- If you are hypersensitive (allergic) to sodium bicarbonate or any of the other ingredients of SODIUM BICARBONATE INJECTION FRESENIUS (listed in section 6)
- if you have kidney failure
- if you have high blood pressure
- if you suffer from fluid retention (swelling)
- if you have heart failure
- if your breathing is slower or more shallow than usual (hypoventilation)
- if your blood is more alkaline than usual
- if you have had kidney stones
- if you have blood abnormalities such as low levels of potassium, chloride or calcium, or high levels of sodium
- if you are losing chloride by vomiting or from continuous gastrointestinal suction
- if you have low levels of stomach acid
- if you are receiving water pills (diuretics) known to lower chloride levels in your blood.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you have impaired kidney function because administration of SODIUM BICARBONATE INJECTION FRESENIUS may cause too high levels of sodium in your blood
- if you are pregnant and developed high blood pressure

- if you have aldosteronism, a condition where your body creates too much of the hormone aldosterone, resulting in too much sodium and fluid in your blood
- if you have reduced urine production or failure to produce urine.

Children

Rapid injection of SODIUM BICARBONATE INJECTION FRESENIUS into babies and children under two years of age may result in too much sodium in the blood, reduced pressure of the fluid that surrounds the brain and possible bleeding inside the scull. Your doctor will therefore limit the rate of administration.

Other medicines and SODIUM BICARBONATE INJECTION FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

- Corticosteroids - used to treat rheumatoid arthritis, inflammatory bowel disease (IBD), asthma, allergies, and other conditions.
- Corticotrophin – used to treat hormone problems.
- Medicines used to treat infections (tetracyclines), especially doxycycline.
- Aspirin (acetylsalicylic acid).
- Chlorpropamide – used to treat diabetes mellitus.
- Lithium - used to treat mood swings and some forms of depression.
- Methenamine – used to treat urinary tract infections.
- Quinidine, flecainide – used to treat heart problems.
- Amphetamines – used to treat certain mental disorders and drowsiness.
- Ephedrine and pseudoephedrine – used to treat colds and asthma.
- Memantine – used to treat Alzheimer’s disease.

- Mecamylamine – used to treat high blood pressure.
- Medicines used to treat water retention and problems with passing urine such as bumetamide, ethacrynic acid, furosemide, and thiazides.
- Potassium supplements.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before receiving SODIUM BICARBONATE INJECTION FRESENIUS.

Driving and using machines

Not applicable. SODIUM BICARBONATE INJECTION FRESENIUS is intended for use only in emergencies.

SODIUM BICARBONATE INJECTION FRESENIUS contains sodium

SODIUM BICARBONATE 4 % INJECTION FRESENIUS contains 10,95 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0,55 % of the recommended maximum daily dietary intake of sodium for an adult.

SODIUM BICARBONATE 8,5 % INJECTION FRESENIUS contains 23,27 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 1,16 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive SODIUM BICARBONATE INJECTION FRESENIUS

Your doctor will give you SODIUM BICARBONATE INJECTION FRESENIUS by slow injection into a vein (intravenous injection).

Your doctor will decide how much SODIUM BICARBONATE INJECTION FRESENIUS you should be given.

You will not be expected to give yourself SODIUM BICARBONATE INJECTION FRESENIUS. It will be given to you by a person who is qualified to do so.

If you receive more SODIUM BICARBONATE INJECTION FRESENIUS than you should

Since a healthcare provider will administer SODIUM BICARBONATE INJECTION FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive SODIUM BICARBONATE INJECTION FRESENIUS

Since a healthcare provider will administer SODIUM BICARBONATE INJECTION FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

SODIUM BICARBONATE INJECTION FRESENIUS can have side effects.

Not all side effects reported for SODIUM BICARBONATE INJECTION FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SODIUM BICARBONATE INJECTION FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving SODIUM BICARBONATE INJECTION FRESENIUS and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- rash or itching,

- fainting,
- seizures in epileptic patients,
- bleeding inside the scull in babies.

These are all very serious side effects. If you have them, you may have had a serious reaction to SODIUM BICARBONATE INJECTION FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Shortness of breath and muscle weakness because of low potassium levels in your blood.
- Stiff arms or legs with difficulty in movement, twitching, involuntary contraction of muscles and 'pins and needles' in your hands or feet.
- Feeling hungry, thirsty, nervous, confused, extreme irritation, increased urination, shakiness or sweating caused by low levels of blood sugar and high concentration of sodium in your blood.
- A blood disorder consisting of an increase in the volume of circulating blood.
- An increased rate of breathing (intracellular acidosis) caused by too much acid in your blood.
- Abnormal heart rhythm or chest pain caused by too much fluid in your blood.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Pain, redness or irritation of the skin caused by the medicine leaking out of the veins into the surrounding tissue.
- Infection or sores on the skin surrounding the injection site.
- Dying of the skin around the injection site if the medicine is not correctly injected.

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

Reporting of side effects

Patients are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SODIUM BICARBONATE INJECTION FRESENIUS.

5. How to store SODIUM BICARBONATE INJECTION FRESENIUS

- Store at or below 25 °C.
- Use immediately after the bag is opened.
- Discard any unused portion.
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What SODIUM BICARBONATE INJECTION FRESENIUS contains

The active substance is sodium bicarbonate.

Each 50 mL of SODIUM BICARBONATE 4 % INJECTION FRESENIUS contains 2 g sodium bicarbonate.

Each 50 mL of SODIUM BICARBONATE 8,5 % INJECTION FRESENIUS contains 4,25 g sodium bicarbonate.

The other ingredients are disodium edetate, carbon dioxide (for pH-adjustment) and water for injection.

Sugar free.

What SODIUM BICARBONATE INJECTION FRESENIUS looks like and contents of the pack

A clear colourless solution.

50 mL solution for injection in 50 mL “Alka” (PVC) bags or **free***flex*® (polypropylene) bags. Each bag is labelled and overwrapped. The overwrapped bags are packed into corrugated cardboard shipper boxes.

Pack sizes of 10, 50 or 60.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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SODIUM BICARBONATE 8,5 % INJECTION FRESENIUS: U/24/235

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.