

Sodium Bicarbonate Injection BP Minijet, 4.2 % w/v & 8.4 % w/v Solution for Injection
Sodium Bicarbonate
Patient Information Leaflet

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or nurse
- 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
- In this leaflet, Sodium Bicarbonate Injection BP Minijet, Solution for Injection will be called Sodium Bicarbonate Injection.

In this leaflet:

1. What Sodium Bicarbonate Injection is for
2. Before you are given Sodium Bicarbonate Injection
3. How Sodium Bicarbonate Injection will be given to you
4. Possible side effects
5. How to store Sodium Bicarbonate Injection
6. Further information.

1. WHAT SODIUM BICARBONATE INJECTION IS FOR

Sodium bicarbonate is a simple chemical which is used in medicine when your blood contains too much acid.

Sodium bicarbonate is used to reduce the amount of acid in the body after a heart attack in patients who have the following conditions: too much acid in their body or too much potassium in their blood.

It can also be used to treat patients who have taken too much tricyclic antidepressant medicine. Sodium Bicarbonate will only be used after other resuscitation methods have been attempted.

2. BEFORE YOU ARE GIVEN SODIUM BICARBONATE INJECTION

Do not use Sodium Bicarbonate Injection if:

- You are allergic to sodium bicarbonate
- You have kidney failure
- You have heart failure
- You have high blood pressure
- You have low blood calcium, potassium or chloride
- You have high blood sodium or pH
- You have had kidney stones
- You suffer from fluid retention
- You suffer from breathing problems (hypoventilation)

If any of these applies to you talk to your doctor or nurse.

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

- Corticosteroids or Corticotrophin
- Medicines of an acidic nature (e.g. tetracycline, doxycycline or methenamine)
- Heart tablets (e.g. quinidine, flecainide)
- Stimulants (e.g. amphetamines)
- Decongestants (e.g. ephedrine or pseudoephedrine)
- Water tablets (e.g. bumetamide, ethacrynic acid, frusemide or thiazides)
- Aspirin (Acetylsalicylic acid)

- Medicines used to treat diabetes mellitus (e.g. chlorpropamide)
- Medicines used to treat mood disorders (e.g. lithium)
- Medicines used to treat high blood pressure (e.g. mecamylamine)
- Medicines used to treat Alzheimers disease (e.g. memantine)
- Potassium supplements
- Any other medicine, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breastfeeding.

Sodium Bicarbonate Injection will only be given to you if your doctor considers the benefit of treatment outweighs the risk to the developing or new born baby.

Important information about one of the ingredients

The 8.4% Sodium Bicarbonate Injection contains 22.9 mg of sodium per ml. The 4.2% Sodium Bicarbonate Injection contains 11.5 mg of sodium per ml. To be taken into consideration by patients on a controlled sodium diet.

3. HOW SODIUM BICARBONATE INJECTION WILL BE GIVEN TO YOU

Important: Sodium Bicarbonate Injection will be given to you by a doctor or nurse. Your doctor will choose the dose that is right for you

- Sodium Bicarbonate is injected into a vein.
- How much you are given depends on how much you need to counteract the acid build-up in your blood.

Adults and the elderly

- The usual starting dose is 1mmol for every kg you weigh
- Followed by 0.5 mmol/kg given at 10minute intervals

Children

- The usual dose is 1 mmol for every kg you weigh given by slow IV injection.

If you think you have been given more Sodium Bicarbonate Injection than you should

As this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too little or too much. However, if you think you have been given too much of this medicine, please tell your doctor.

Signs of too much sodium bicarbonate include hyperventilation (over breathing), very sensitive to slight stimuli, twitching and high potassium levels in your blood which may cause you to feel dizzy or tired.

If you have any further questions about the use of this medicine, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines Sodium Bicarbonate Injection can cause side effects, although not everybody gets them.

Side effects include:

- Low levels of potassium causing twitching, muscle weakness, ‘pins and needles’ in the hands or feet, irritability or abnormal heart rhythm
- Low levels of blood sugar causing feeling hungry, thirsty, nervous, confused, extreme irritation, increased urination, shakiness or sweating
- Involuntary contraction of your muscles.
- Swelling due to a build-up of fluid under the skin
- New born babies may have bleeding inside the skull

- Sodium bicarbonate may leak out of the veins into the surrounding tissue. This may cause pain, redness or irritation to the skin
- If the medicine is not correctly injected it could cause the skin to die around the injection site.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SODIUM BICARBONATE INJECTION

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date on the carton and syringe label. The expiry date refers to the last day of that month.

Store below 25°C. Do not refrigerate.

For single use only. The product should be used immediately after opening. Discard any unused portion.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

6. FURTHER INFORMATION

What Sodium Bicarbonate Injection contains

The active substance is sodium bicarbonate.

There are two strengths of sodium bicarbonate:

- The 4.2% strength contains 42 mg in each ml of solution.
- The 8.4% strength contains 84 mg in each ml of solution.

The only other ingredient is: 'water for injections'.

What Sodium Bicarbonate Injection looks like

Sodium Bicarbonate Injection is a clear and colourless sterile solution. It comes in various different pack sizes as follows:

8.4% strength in a 10 ml clear glass syringe with a luer lock connector

8.4% strength in a 50 ml clear glass vial with a separate injector.

4.2% strength in a 10 ml clear glass vial with a separate injector.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

DLRC Pharma Services Limited, Chesterfield House, Clonmannon, ASHFORD, County Wicklow, A67WR29, Ireland

Manufacturer

UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK

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If this leaflet is difficult to see or read or you would like it in a different format, please contact: DLRC Pharma Services Limited, Chesterfield House, Clonmannon, ASHFORD, County Wicklow, A67WR29, Ireland