Package leaflet: Information for the user

Sodium Bicarbonate 500 mg Capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet:

- 1. What Sodium Bicarbonate is and what it is used for
- 2. What you need to know before you take Sodium Bicarbonate
- 3. How to take Sodium Bicarbonate
- 4. Possible side effects
- 5. How to store Sodium Bicarbonate
- 6. Contents of the pack and other information

1. What Sodium Bicarbonate is and what it is used for

Sodium Bicarbonate belongs to a group of drugs known as antacids. Sodium Bicarbonate capsules are used to treat:

- indigestion
- acidosis (a condition where the body fluids and tissues are unusually acid).

2. What you need to know before you take Sodium Bicarbonate Warnings and precautions

Talk to your doctor before you start to take this medicine if you:

- have kidney problems
- have liver problems
- suffer from high blood pressure or heart failure
- are elderly
- are on a low sodium (salt) diet (see also 'Sodium Bicarbonate contains sucrose and sodium' below).

Please talk to your doctor if your symptoms remain the same after taking this medicine.

Other medicines and Sodium Bicarbonate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor if you are taking any of the following:

- antibiotics or antifungals (to treat an infection) e.g. rifampicin, ketoconazole, tetracycline
- phenothiazines (to treat anxiety or depression)
- corticosteroids (to treat swelling and inflammation or for allergic reactions)
- lithium (for mental illness)
- aspirin

- methotrexate (for certain types of tumours, psoriasis or rheumatoid arthritis)
- quinidine or dipyridamole (to treat heart rhythm disorders)
- ephedrine (to treat breathing problems)
- phenytoin (for epilepsy)
- chloroquine (to prevent or treat malaria)
- penicillamine (for rheumatism)
- dipyridamole (to prevent blood clots associated with heart problems).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Sodium Bicarbonate is not known to affect your ability to drive or operate machinery.

Sodium Bicarbonate contains sucrose and sodium

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Talk to your doctor or pharmacist if you need three or more capsules daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take Sodium Bicarbonate

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you Check with your doctor or pharmacist if you are not sure.

Do not take more than the prescribed dose.

Do not take the capsules for too long without seeing your doctor. If your indigestion does not get any better after taking the capsules, go and see your doctor.

The capsules should be swallowed with a drink of water. The recommended dose is:

Adults

- Indigestion
- Between 1 g and 5 g (2 to 10 capsules) when needed.
- Acidosis

Your doctor will calculate the appropriate dose for you.

Elderly

If you are elderly, you should consult your doctor before taking this medicine, and must be particularly careful to follow your doctor's instructions.

Children

Sodium Bicarbonate is not recommended for use in children.

If you take more Sodium Bicarbonate than you should

If you (or someone else) swallow a lot of the capsules all together, or if you think a child has swallowed any of the capsules, contact your nearest hospital casualty department or your doctor immediately. A severe overdose is likely to cause shortness of breath, muscle weakness, uncontrolled shaking of body and prolonged unconsciousness.

Please take this leaflet, any remaining capsules, and the container with you to the hospital or doctor so that they know which capsules were consumed.

If you forget to take Sodium Bicarbonate

If you have been prescribed regular doses of this medicine, and you forget to take your dose at the correct time, take your dose as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens, stop taking the capsules and tell your doctor immediately or go to the casualty department at your nearest hospital:

• an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor if you suffer from any of the following for more than a few days:

- stomach pains
- feeling bloated
- belching
- wind.

The following effects may also occur:

- if you use Sodium Bicarbonate for a long time, your body tissues and fluids may become too alkaline. This is called alkalosis and you may notice muscle weakness and cramps.
- Sodium Bicarbonate capsules contain a lot of sodium, which could make your blood pressure go up or cause fluid accumulation in your body and lungs.
- if you already have a low level of potassium in your blood (hypokalaemia), Sodium Bicarbonate capsules may make this worse.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Sodium Bicarbonate

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original container.

Do not use Sodium Bicarbonate after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information What Sodium Bicarbonate capsules contain:

• The active substance is sodium bicarbonate 500 mg.

• The other ingredients are sucrose, colloidal silicon dioxide, and magnesium stearate. The capsule shell contains gelatin and titanium dioxide (E171). The printing ink contains shellac, black iron oxide (E172) and propylene glycol (E1520).

What Sodium Bicarbonate capsules look like and contents of the pack:

- The Sodium Bicarbonate capsules are white capsules. They are printed 'SDB 500' and 'Twin Triangle Logo' or unmarked.
- They come in packs of 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 250, 500, or 1000 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer Marketing Authorisation holder:

TEVA UK Limited, Eastbourne, BN22 9AG

Manufacturer:

Teva Pharmaceutical Works Private Limited Company, 4042 Debrecen, Pallagi út 13, Hungary.

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