

Patient package insert according to Pharmacists' Regulations (Preparations) -1986

This medicine can be sold without a physician's prescription

SODIUM BICARBONATE 500 mg, Tablets

Composition:

Each tablet contains: Sodium Bicarbonate 500 mg.

Each tablet contains approximately 137 mg Sodium.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

Take this medicine according to the instructions in section 3 "How to use this medicine?" in this leaflet. Consult the pharmacist if you need additional information. Refer to a doctor if the symptoms of your illness get worse or if they do not improve after 14 days.

1. What is the medicine intended for?

The medicine **Sodium Bicarbonate 500 mg** is intended for relief in cases of hyperacidity in the stomach.

Therapeutic group: Antacid.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (Sodium Bicarbonate) or to any of the other ingredients this medicine contains (see section 6 "Additional information").

Special warnings regarding the use of this medicine

Before using Sodium Bicarbonate 500 mg, tell the doctor if:

- You have previously suffered from heart failure
- You suffer from liver or kidney problems
- You have high blood pressure
- You are on a low salt diet (each tablet contains approximately 137 mg of Sodium)
- You are elderly

Children and adolescents:

The medicine is not recommended for use in children and infants under 6 years of age.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Drugs containing Lithium (for depression)
- Phenothiazines (to treat anxiety)
- Antibiotics (e.g., Rifampicin or Tetracycline)
- Anti- fungal medicines (e.g., Ketoconazole, Itraconazole)
- Drugs to treat high blood pressure (e.g Captopril, Enalapril)
- Dipyridamole (to prevent blood clotting)
- Quinidine (for heart rhythm disturbances)
- Phenytoin and Gabapentin (for epilepsy)
- Chloroquine and Hydroxychloroquine (to prevent or treat malaria or for arthritis)
- Penicillamine (for rheumatism)
- Bisphosphonates (to treat Pagets disease, in which bones form too quickly or to treat established osteoporosis to slow down bone loss)
- Methotrexate (used in cancer treatment)
- Ephedrine (used in cold remedies/ nasal decongestants)
- Aspirin

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or planning to become pregnant, consult a doctor or pharmacist before starting to use this medicine.

Driving and using machines:

The medicine is not expected to affect your ability to drive or operate machines.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The usual dosage, in adults and children above 6 years old, is generally:

1-4 tablets, 4 times daily, as needed.

Do not use this medicine frequently or for an extended period (over 14 days) without consulting a doctor.

Do not exceed the recommended dose.

Method of administration:

- Swallow the tablet with a glass of water.
- For ease of swallowing, the tablet may be halved or crushed, for immediate use. No information is available regarding the uniformity of split halves of the tablet.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

Symptoms of overdose include in severe cases, mood changes, shortness of breath, muscle weakness, twitching, tiredness, irregular heartbeat, convulsions and prolonged unconsciousness.

If you forget to take the medicine

If you forgot to take the medicine at the designated time, do not take a double dose to make up for a forgotten dose, take the next dose at the regular time.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of **Sodium Bicarbonate 500 mg** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking this medicine and refer to the doctor or to a hospital emergency room immediately with the appearance of one or more of the following serious side effects:

- Low potassium (hypokalaemia), symptoms may include an abnormal heartbeat, muscle weakness and numbness
- Fluid in the lungs (pulmonary oedema)
- Increased blood pressure

Additional side effects:

- Stomach pains
- Flatulence
- Alkalosis (an increase in pH of the blood), symptoms may include tiredness/ weariness, vomiting, thirst and restlessness (possibly due to prolonged use, which is not advised)

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:

- Store in a dry place and below 25°C.
 - The medicine can be used for up to 60 days after the package is first opened, and no later than the expiry date (exp. Date) that appears on the package.
 - Store the medicine in the original package.
 - Keep the package tightly closed after each use to protect from moisture.
 - The package contains desiccant (moisture absorbent). Do not swallow the desiccant or take it out of the package.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Starch, Magnesium Stearate, Croscarmellose Sodium (Ac-Di-Sol), Acacia, Talc.

What the medicine looks like and what the package contains:

A white round biconvex tablets, "REKAH" engraved on one side and plain on the other.

Approved package size: Each package contains 100 tablets.

Manufacturer and registration holder:

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon, 5881904, Israel.

Revised in July 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

022-07-23524-00