

Patient Leaflet According to the Pharmacists' Regulations (Preparations) -
1986

This medicine is sold with a doctor's prescription only

Pyridostigmine 30
Pyridostigmine 60
Tablets

Active ingredient:

Each tablet of Pyridostigmine 30 contains: Pyridostigmine bromide 30 mg

Each tablet of Pyridostigmine 60 contains: Pyridostigmine bromide 60 mg

For a list of the other ingredients, please see section 6.

See also 'Important information about some of the medicine's ingredients in section 2.

Read this entire leaflet carefully before using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

The medicine is intended for the treatment of myasthenia gravis.

Therapeutic group: cholinesterase inhibitors.

The tablets contain the active ingredient pyridostigmine bromide which acts as an inhibitor of the enzyme cholinesterase and thus prevents the increased degradation of acetyl choline, a substance which transmits pulses from the nerve to the muscle.

In patients who suffer from myasthenia gravis the muscles quickly become tired and weak. In severe cases, they even reach a state of muscle paralysis.

2. Before you take the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).
- You suffer from a mechanical obstruction of the intestines or the urinary tract.

Special warnings regarding the use of this medicine:

- If you are about to undergo surgery, notify the medical team that you are taking this medicine.

Before starting the treatment with Pyridostigmine tell your doctor if:

- You suffer from asthma or other problems of the respiratory system such as wheezing, breathing difficulties, chronic cough, chronic obstructive pulmonary disease/COPD;
- You have recently had a myocardial infarction (heart attack) or you suffer from arrhythmia, slow heart rate or any other medical condition associated with the heart (the older population is more sensitive to changes in heart rate);
- You suffer from low blood pressure;
- You suffer from a stomach ulcer;
- You suffer from epilepsy;

- You suffer from Parkinson's disease;
- You suffer from kidney problems;
- You suffer from vagotonia which is a condition of hyperactivity of the vagus nerve, which causes a slowing of the heart rate, low blood pressure, constipation, sweating and painful muscle contractions;
- You suffer from an overactive thyroid gland;
- You have had surgery for the removal of the thymus gland.

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Steroid medicines or other medicines which suppress the immune system;
- Antimuscarinic medicines (e.g. atropine, hyoscine);
- Medicines containing methyl-cellulose;
- Certain antibiotics e.g. antibiotics from the aminoglycoside group (such as gentamycin);
- Medicines to treat arrhythmia (irregular heart beat);
- Anesthetics for surgery, local anesthetics;
- Other medicines which affect conductivity between nerve and muscle;
- Medicines to relax the muscles during surgery e.g. pancuronium or vecuronium: if you are about to have surgery, tell your doctor that you are taking Pyridostigmine. In addition, Pyridostigmine may prolong the effect of other muscle relaxants e.g. suxamethonium.

Pregnancy and breastfeeding:

Consult with your doctor if you are pregnant, think you are pregnant or planning a pregnancy.

Consult with your doctor if you are breastfeeding, since the medicine passes into breast milk in small amounts.

Driving and use of machinery: The medicine may impair sharpness of vision and therefore impair your ability to drive or to operate machinery. In the event the medicine affects your vision, do not drive or operate machinery.

Important information about some of the medicine's ingredients:

The tablets contain lactose. If you are sensitive to lactose, tell your doctor before taking the medicine (see section 6).

3. How should this medicine be used?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and the manner of treatment will be determined by the doctor only.

The medicine should be taken at set intervals as determined by the attending doctor.

The standard dosage is usually:

The dosage will be determined by your doctor. The medicine takes 30-60 minutes until it begins to take effect from the moment you take the determined dose. The effect lasts between 4 to 6 hours. Therefore, consult with your doctor about the optimal times for taking the medicine, so that it will have an effect when there is need for the muscles to work, for example, 30-60 minutes before a meal.

Do not exceed the recommended dose.

There is no information regarding crushing or chewing of the tablets.

Do not halve the tablets since there is no score line. (If there is need to divide the tablet in order to make it easier to swallow, make sure to take all the pieces of the tablet).

Swallow the medicine with water.

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

If you forgot to take this medicine at the set time, take a dose as soon as you remember. Take the next dose at the regular time. Do not take a double dose to make up for the forgotten dose. If you have forgotten more than one dose, consult with your doctor.

Continue with the treatment as recommended by your doctor. Even if your state of health improves, do not stop taking the medicine without consulting with your doctor.

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 any further questions regarding the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like any medicine, the use of Pyridostigmine 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.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Vision disturbances, excessive secretion of tears, miosis (constriction of pupils);
- Irregular heartbeat, heart block, low blood pressure, fainting, bradycardia (slow heart rate), tachycardia (rapid heart rate);
- Excessive secretion of phlegm and constriction of the airways;
- Nausea, vomiting, diarrhea, abdominal cramps, excessive secretion of saliva;
- Rash;
- Excessive sweating;
- Muscle weakness and twitching, tremors and muscle cramps;
- Sudden compelling urge to urinate.

If side effects appear, if one of the side effects worsens or when you suffer from side effects which have not been mentioned in this leaflet, consult with your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the link:

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 of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C in the original package.

6. Additional information

In addition to the active ingredient, the medicine also contains the following ingredients:

Lactose, corn starch, stearic acid, silicon dioxide, ethyl cellulose, magnesium stearate.

Each tablet of Pyridostigmine 30 contains approximately 50 mg lactose.

Each tablet of Pyridostigmine 60 contains approximately 100 mg lactose.

What does the medicine look like and what does the package contain?

Pyridostigmine 30: white round tablets in blister packs; package of 21 tablets.

Pyridostigmine 60: white round tablets in blister packs; package of 30 tablets.

Registration holder: Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.

Medicine registration number in the National Drug Registry of the Ministry of Health:

Pyridostigmine 30: 0517725053 Pyridostigmine 60: 1454131869

This leaflet was checked and approved by the Ministry of Health in March 2017.