

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is to be supplied by physician's prescription only

Mestinon Dragees 60 mg

Active ingredient:

Pyridostigmine bromide 60 mg

For the list of inactive ingredients – see section "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

What is this medicine used for?

Mestinon is indicated for treatment of Myasthenia gravis.

Therapeutic group:

Cholinesterase inhibitors.

Mestinon contains the active ingredient Pyridostigmine bromide which acts as an inhibitor of cholinesterase. This prevents the rapid metabolism of acetylcholine, which is a substance that transmits pulses from the nerve to the muscle.

Patients who have Myasthenia gravis feel that their muscles are weak and tired easily. In severe cases, muscle paralysis may occur.

Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient Pyridostigmine bromide or to any of the other ingredients that this medicine contains (see section "Additional information").
- You have a mechanical obstruction of the gastrointestinal or urinary tract.

Special warnings regarding the use of this medicine

Before starting treatment with Mestinon, tell your physician if:

- You suffer from asthma or other problems in your respiratory system such as wheezing, breathing difficulties, chronic cough
- You have recently had a myocardial infarction (heart attack), or if you suffer from slow heartbeat or any other medical condition related to your heart (older people are 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, a condition in which the vagus nerve is overactive. This causes a slower heart rate, low blood pressure, constipation, sweating, and painful muscle spasms
- You suffer from overactive thyroid gland
- You have had surgery to remove your thymus gland

If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, inform your physician or pharmacist. In particular, inform the physician or the pharmacist if you are taking:

- Steroids or any other medicine that suppresses the immune system
- Antimuscarinic medicines such as atropine
- Medicines that contain methyl cellulose
- Antibiotics, especially aminoglycosides
- Medicines for treating irregular heart beat
- Medicines that affect nerve conduction
- Medicines for relaxing your muscles during surgery such as pancuronium or vecuronium. If you are having surgery, inform your physician that you are taking **Mestinon**. In addition, **Mestinon** may cause other muscle relaxing medicines, such as suxamethonium, to have a prolonged effect.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or planning to become pregnant, you should consult the physician. Consult your physician if you are breastfeeding, because small amounts of **Mestinon** pass into breast milk.

Driving and using machines

Using **Mestinon** can reduce sharpness of your vision and this can impair your ability to drive or operate machines. Do not drive or operate machines if you think this medicine has influenced your vision.

Important information about some of the medicine's ingredients

Mestinon contains sucrose. If your physician has told you that you are intolerant to certain sugars, consult your physician before starting treatment with **Mestinon**.

Do not use **Mestinon** if you have an inherited intolerance to fructose/ galactose, glucose-galactose or sucrase-isomaltase absorption problems.

How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or with the pharmacist if you are not sure.

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

Do not exceed the recommended dose.

Do not split the dragees.

Swallow the dragees with water or any other non-alcoholic beverage.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed the medicine, go immediately to a physician or to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your physician.

If you forget to take more than one dose consult your physician.

Persist with the treatment as recommended by the physician.

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

If you have any further questions regarding the use of this medicine, consult the physician or the pharmacist.

Side effects

As with any medicine, the use of **Mestinon** may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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

- Vision disturbance, increased discharge of tears, miosis (narrowing of the pupils)
- Irregular heart rate, heart block, low blood pressure, fainting, bradycardia (slow heart rate), tachycardia (fast heart rate)
- Increased discharge of mucus and constriction of the airways
- Nausea, vomiting, diarrhoea, stomach cramps, producing more saliva than usual
- Rash
- Increased sweating

- Muscle weakness and twitching, muscle tremors, muscle cramps
- Sudden and strong urge to urinate

If any side effect appears, if any side effects worsen, or if you suffer from a side effect not mentioned in this leaflet, you should consult the physician.

Reporting side effects:

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a close place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the outer package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Store in the original package.
- Use for 3 months after first opening.
- Close the bottle firmly to protect the contents from moisture.

Additional information

- In addition to the active ingredient Pyridostigmine bromide, the medicine also contains: Maize starch, Magnesium stearate, Pregelatinised starch, Povidone K 30, Colloidal anhydrous silica, Talc, Acacia spray-dried gum, Iron oxide red (E 172), Iron oxide yellow (E 172), Light liquid paraffin, Hard paraffin, Rice starch, Sucrose crystalline.
- What does the medicine look like and what are the contents of the package:
Film-coated orange to light-orange, round, convex tablets, packaged in a glass bottle containing 20 or 150 dragees.
- Registration holder name and address: MegaPharm Ltd., P.O.B. 519, Hod Hasharon 4510501.
- Manufacturer name and address: ICN Polfa, Rzeszow, Poland **for** MEDA Pharma GmbH & Co., Bad Homburg, Germany.
- This leaflet was checked and approved by the Ministry of Health in May 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 130-84-21200 .