

Package leaflet: Information for the user**Mestinon® 60 mg Tablets**

pyridostigmine bromide

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

- * Keep this leaflet. You may need to read it again.
- * If you have any further questions, ask your doctor or pharmacist.
- * This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- * If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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1 What Mestinon Tablets are and what they are used for

Mestinon tablets contain the active ingredient pyridostigmine, which belongs to a group of medicines called anticholinesterases, which improve the communication between the nerves and muscles.

Mestinon tablets are used for:

- * Treatment of myasthenia gravis – a disease of the immune system causing muscle weakness
- * Paralytic ileus – a condition where the digestive tract does not work because its muscles are paralysed
- * Urinary retention after surgery – failure to urinate caused by an anaesthetic or certain types of surgery.

2 What you need to know before you take Mestinon tablets**Do not take Mestinon tablets:**

- If your digestive tract is twisted or blocked by an obstruction.
- If you cannot pass urine because of an obstruction.
- If you are allergic to pyridostigmine, bromine, or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before taking Mestinon tablets if you have any of the following conditions:

- Obstructive respiratory diseases such as bronchial asthma or chronic obstructive pulmonary disease (COPD)
- Bradycardia – a slow heart rate
- A recent blockage of a blood vessel to the heart
- Low blood pressure
- Epilepsy
- Stomach ulcer
- Parkinson's disease
- Vagotonia – a disturbance of the vagus nerve causing constipation, sweating and muscle spasms
- Irregular heartbeat, especially if you are elderly
- Kidney disease – you may need a lower dose.
- Hyperthyroidism
- Renal impairment

Other medicines and Mestinon tablets

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

If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed. Tell your doctor or pharmacist if you are taking:

- Anticholinergic drugs such as atropine or hyoscine (commonly used in the treatment of vomiting or diarrhoea)
- Muscle relaxants such as pancuronium, vecuronium, or suxamethonium.

Pregnancy and breast-feeding

If you are pregnant or you think you may be pregnant, you should inform your doctor who will decide whether or not you should not be given Mestinon tablets.

A small amount of Mestinon is found in breast milk so you should ask your doctor's advice before 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.

Mestinon tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Mestinon tablets.

3 How to take Mestinon tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose of Mestinon depends on the condition for which it is being used.

Adults and the elderly

Myasthenia gravis (muscle weakness): The usual adult dose is between 5 and 20 tablets 300-1200 mg) per day.

Paralytic ileus and urinary retention after surgery: The usual dose is 1 to 4 tablets (60 to 240 mg) per day.

Special patient groups:

If you have kidney problems, you may be given a lower dose. If you have had an operation to remove the thymus or if you are taking immunosuppressants or steroids you may also be given a lower dose.

Use in Children

Myasthenia gravis (muscle weakness): Children under 6 years old should receive an initial dose of half a tablet (30 mg) of Mestinon; children 6-12 years old should receive one tablet (60 mg). Dosage should be increased gradually, by 15-30 mg daily, until the best improvement is obtained. The total daily dose is usually between 30-360 mg (half to 6 tablets).

The tablets are taken during the day when maximum strength is needed, for example, getting up and before mealtimes. Mestinon tablets should be taken with water (half full to full glass of water).

Paralytic ileus and urinary retention after surgery: The usual dose is one quarter to 1 tablet (15 to 60 mg) per day.

If you take more Mestinon tablets than you should

Contact your doctor straight away. Signs of overdose are muscle or abdominal (tummy) cramps, diarrhoea, feeling sick, vomiting, increased saliva (mouth liquid), pin-point pupils of the eyes, sweating, muscle twitching, weakness, and slow heart rate.

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

Package leaflet: Information for the user (continued)**Mestinon® 60 mg Tablets**

pyridostigmine bromide

4 Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Rare:

* Rash

Frequency not known:

- * Drug hypersensitivity
- * Syncope (temporary loss of consciousness due to a fall in blood pressure)
- * Miosis, increased lacrimation (eye watering), accommodation disorders (e.g. blurred vision)
- * Arrhythmia (problem with rate or rhythm of the heart) including bradycardia, tachycardia, AV block, Prinzmetal angina
- * Flushing, low blood pressure
- * Increased bronchial secretion combined with bronchoconstriction
- * Nausea, vomiting, diarrhoea, increased saliva production, abdominal symptoms (e.g. discomfort, pain, cramps etc...)
- * Increased sweating
- * Increased muscle weakness, muscle twitching, tremors, muscle cramps, decreased muscle tone
- * Urine urgency
- * Hives

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Mestinon tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the original container after "EXP". The expiry date refers to the last day of that month.

Do not store above 25° C. Store in the original package and keep the bottle tightly closed.

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 Mestinon tablets contain:**

Each tablet contains 60 mg of the active ingredient pyridostigmine bromide. The other ingredients are: lactose monohydrate, silicic acid, corn starch, talc, magnesium stearate and potato starch.

What Mestinon tablets look like and contents of the pack

Mestinon are white to off-white, round, biplanar, bevel-edged tablets imprinted with "V" M60 across one face and with two break marks forming a cross on the other. Mestinon tablets come in amber glass bottles with low density polyethylene caps and desiccant containing 2 x 100 tablets.

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Manufactured by:

Labiana Pharmaceuticals, S.L.U. C/ Casanova, 27-31 08757 - Corbera de Llobregat (Barcelona).

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Phone Lexon Pharmaceuticals (Ireland) Limited,

Tel: +35318710550 for help.