

PACKAGE LEAFLET: INFORMATION FOR THE USER

MESTINON

60mg tablets

PYRIDOSTIGMINE BROMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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?

1. What MESTINON is and what it is used for
2. Before you take MESTINON
3. How to take MESTINON
4. Possible side effects
5. How to store MESTINON
6. Further information

1. WHAT MESTINON IS AND WHAT IS IT USED FOR

Mestinon is used for the treatment of myasthenia gravis. In patients who suffer from myasthenia gravis the muscles quickly become tired and weak and, in severe cases, the muscles may become paralysed. Myasthenia gravis is caused by excessive activity in the body of a protein called cholinesterase.

Mestinon belongs to a group of medicines known as cholinesterase inhibitors. Cholinesterase inhibitors stop the excessive activity of cholinesterase and in this way help muscles to work properly.

Mestinon is also used to treat some **rare forms of constipation** (paralytic ileus) and inability to pass urine after an operation.

2. BEFORE YOU TAKE MESTINON

Do not take Mestinon Tablets if you:

- Are allergic (hypersensitive) to pyridostigmine, bromides or any of the other ingredients of Mestinon Tablets (these are listed in section 6, "Further Information").

- Are constipated or cannot urinate, unless your doctor has told you to use this medicine. This is because Mestinon is only for some types of constipation and inability to pass urine (see Section 1).

Take special care with Mestinon

Before treatment with Mestinon, tell your doctor if you:

- Suffer from asthma or have other chest problems such as wheeziness, difficulty in breathing or chronic cough.
- Have recently had coronary obstruction (heart attack), have a slow heart beat or any other heart condition.
- Have low blood pressure.
- Have a stomach ulcer.
- Have epilepsy.
- Have Parkinson's disease.
- Have kidney problems.
- Suffer from a condition called vagotonia (this is a condition where overactivity of the vagus nerve causes symptoms such as slow heart rate, low blood pressure, constipation, sweating and painful muscle spasms).
- Have an overactive thyroid gland
- Have had an operation to remove your thymus gland.

There is no evidence to suggest that Mestinon has any special effects on elderly patients.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. In particular, tell your doctor if you are taking any of the following medicines:

- Medicines known as steroids or other immunosuppressant medicines.
- Medicines known as antimuscarinics (e.g. atropine, hyoscine).
- Medicines containing methylcellulose
- Antibiotics
- Medicines to treat an irregular heart beat
- Other medicines that interfere with transmission between nerves and muscles

If you are going to have surgery

Tell your doctor that you are taking Mestinon. Mestinon can stop the effect of some medicines used to relax muscles during surgery (e.g. pancuronium, vecuronium).

Mestinon can also prolong the effect of other muscle relaxants (e.g. suxamethonium).

Pregnancy and breast-feeding

Tell your doctor before you start treatment if you:

- Are pregnant, if you think you are pregnant, or if you intend to become pregnant.
- Are breast-feeding, as Mestinon passes into breast milk in small amounts.

Your doctor will then decide if you can take this medicine.

Driving and using machines

Mestinon may reduce the sharpness of your eyesight and therefore your ability to drive or use machines. Do not drive or operate machines if this medicine affects your ability to see clearly.

Important information about some of the ingredients of Mestinon Tablets

Mestinon Tablets contain lactose. Therefore, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE MESTINON

Swallow the tablets with water or another non - alcoholic drink. If you have difficulty swallowing, you can break the tablets into pieces.

You should check with your doctor or pharmacist if you are not sure how to take Mestinon.

The dose will depend on your illness, your needs and on your age as follows:

For myasthenia gravis:

- The usual adult dose is $\frac{1}{2}$ to 2 tablets (30 to 120 mg Mestinon) to be taken five to six times daily, or higher doses if needed, as recommended by your doctor.
- For children under 6 years, the usual dose is $\frac{1}{2}$ a tablet (30 mg). For children aged 6 to 12 years, the usual starting dose is 1 tablet (60 mg). The doctor will then gradually increase the dose until maximum improvement is seen. In children the total dose per day is usually 30 to 360 mg.

The tablets take 30 to 60 minutes to start working after you have taken them.

The effect of each dose should last about four hours during the day and about six hours at night.

You should try to take your medicine so that it can work when your muscles are needed most, for example, when you get up and about 30 to 60 minutes before a meal.

For paralytic ileus (constipation) and post-operative inability to pass urine:

- The usual adult dose is 1 to 4 tablets (60 to 240 mg Mestinon) daily and for children $\frac{1}{4}$ to 1 tablet (15 to 60 mg) daily, depending on the needs of the patient.

If you take more Mestinon than you should

If you take too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

If you forget to take Mestinon

If you forget to take one of your daily doses, take it as soon as you remember, and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose. If you miss more than a single dose, you should contact your doctor for advice.

4. POSSIBLE SIDE EFFECTS

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

Possible side effects with Mestinon:

Side effects of unknown frequency:

- visual disturbance, producing more tears than usual an irregular heart beat, heart block, low blood pressure, fainting
- producing more phlegm than usual combined with constriction of the airways
- feeling sick, vomiting, diarrhoea, stomach cramps, producing more saliva than usual
- rash
- excessive sweating
- muscle weakness and twitching, shaking, muscle cramps
- sudden, compelling urge to urinate.

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 the

Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE MESTINON

Keep Mestinon Tablets out of the reach and sight of children.

Store the bottle in the original outer carton.

Keep the bottle tightly closed in order to protect from moisture.

Do not store above 25 °C.

Do not use Mestinon Tablets after the expiry date which is stated on the bottle label and outer carton after the text "EXP". The expiry date refers to the last day of that month.

Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Mestinon contains

Active substance:

Each tablet contains 60 mg of pyridostigmine bromide.

Other ingredients:

Colloidal hydrated silica, maize starch, lactose monohydrate, talc and magnesium stearate.

What Mestinon looks like and contents of the pack

The tablets are scored on one side so that they can be broken into halves or quarters and "V" is imprinted on the other side.

The tablets come in packs of 200.

A desiccant is enclosed in the bottle.

Manufacturer

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