Patent Information Leaflet

Mestinon® 60mg Tablets
(pyridostigmine bromide)

Please read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects and this becomes serious, tell your doctor or pharmacist.

Your medicine is known as Mestinon 60mg Tablets but will be referred to as Mestinon Tablets throughout this leaflet.

In this leaflet:
1) What Mestinon Tablets are and what they are used for
2) Before you take Mestinon Tablets
3) How to take Mestinon Tablets
4) Possible side effects
5) How to store Mestinon Tablets
6) Further information

1) WHAT MESTINON TABLETS ARE AND WHAT THEY ARE USED FOR

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

2) BEFORE YOU TAKE MESTINON TABLETS

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 Tablets are only for some types of constipation and inability to pass urine (see Section 1).

Take special care with Mestinon Tablets

Before treatment with Mestinon Tablets, 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 Tablets have 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 Tablets. Mestinon Tablets can stop the effect of some medicines used to relax muscles during surgery (e.g. pancuronium, vecuronium). Mestinon Tablets 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 Tablets pass into breast milk in small amounts.

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

Driving and using machines

Mestinon Tablets 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 TABLETS

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 Tablets.

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

For myasthenia gravis:
- The usual adult dose is ½ to 2 tablets (30 to 120 mg Mestinon Tablets) 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 ½ 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 Tablets) daily and for children ¼ to 1 tablet (15 to 60 mg) daily, depending on the needs of the patient.

**If you take more Mestinon Tablets 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 Tablets**
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 Tablets can cause side effects, although not everybody gets them.

**Possible side effects with Mestinon Tablets**
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 TABLETS

- Keep all medicines out of the sight and reach of children.
- Do not store above 25°C.
- Store in the original package in order to protect from light and moisture. Keep the bottle tightly closed.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Do not use Mestinon Tablets after the expiry date which is stated on the bottle label and the outer carton after the text “EXP”. The expiry date refers to the last day of that month.
- Medicines should 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
- If your medicine gets discoloured or shows any other signs of deterioration, seek the advice of your pharmacist.

### 6) FURTHER INFORMATION

**What Mestinon Tablets contain**
The active substance in Mestinon Tablet is pyridostigmine bromide.
Each tablet contains 60 mg of pyridostigmine bromide.
The other ingredients are: silicic acid, maize starch, lactose, talc, magnesium stearate and pregelatinised potato starch.

**What Mestinon Tablets looks like and contents of the pack**
Mestinon Tablets come in an amber glass bottle with plastic screw cap and security seal. Mestinon Tablets 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 60mg Tablets are available in packs of 100.

**Manufactured by:**

**Procured from within the EU & repackaged by Product Licence holder:**
Kosei Pharma UK Ltd., 956 Buckingham Avenue, Slough Trading Estate, Slough, SL1 4NL

**Mestinon® 60mg Tablets, PL 39352/0191**

Mestinon® is a registered trademark of Valeant Pharmaceuticals International, USA.

Leaflet date: 20.08.2014

**POM**
PATIENT INFORMATION LEAFLET

Pyridostigmine bromide
60mg Tablets

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- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you experience any side effects and this becomes serious, tell your doctor or pharmacist.

Your medicine is known as Pyridostigmine bromide 60mg Tablets but will be referred to as Pyridostigmine bromide Tablets throughout this leaflet.

In this leaflet:
1) What Pyridostigmine bromide Tablets are and what they are used for
2) Before you take Pyridostigmine bromide Tablets
3) How to take Pyridostigmine bromide Tablets
4) Possible side effects
5) How to store Pyridostigmine bromide Tablets
6) Further information

1) WHAT PYRIDOSTIGMINE BROMIDE TABLET ARE AND WHAT THEY ARE USED FOR
Pyridostigmine bromide Tablets are 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. Pyridostigmine bromide Tablets belong 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. Pyridostigmine bromide Tablets are also used to treat some rare forms of constipation (paralytic ileus) and inability to pass urine after an operation.

2) BEFORE YOU TAKE PYRIDOSTIGMINE BROMIDE TABLETS
Do not take Pyridostigmine bromide Tablets if you:
- Are allergic (hypersensitive) to pyridostigmine, bromides or any of the other ingredients of Pyridostigmine bromide 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 Pyridostigmine bromide Tablets are only for some types of constipation and inability to pass urine (see Section 1).

Take special care with Pyridostigmine bromide Tablets
Before treatment with Pyridostigmine bromide Tablets, 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 Pyridostigmine bromide Tablets have 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.

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Important information about some of the ingredients of Pyridostigmine bromide Tablets
Pyridostigmine bromide 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 PYRIDOSTIGMINE BROMIDE TABLETS
Swallow the tablets with water or another non-alcoholic drink. If you have difficulty swallowing, you can break the tablets into pieces.

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