Package leaflet: Information for the user

Pyridostigmine Bromide 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 symptoms 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. See section 4.

What is in this leaflet

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1. What Pyridostigmine Bromide Tablets 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 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.

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

2. What you need to know before you take Pyridostigmine Bromide Tablets

Do not take Pyridostigmine Bromide Tablets
- if you are **allergic to pyridostigmine bromide**, or any of the other ingredients of this medicine (listed in section 6)
- if you 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 and consult 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 (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.

Other medicines and Pyridostigmine Bromide Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 medicine.

It is extremely important that you tell your doctor if you are taking any medication, in particular:
- 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 heartbeat,
- other medicines that interfere with transmission between nerves and muscles.

If you are going to have surgery, please tell your doctor as pyridostigmine bromide can stop the effect of some medicines used to relax muscles during surgery (e.g. pancuronium, vecuronium).

Pyridostigmine bromide 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, think you may be pregnant or are planning to have a baby,
- are breast feeding, as pyridostigmine bromide passes into breast milk in small amounts.

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

Driving and using machines
Pyridostigmine Bromide 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.

Pyridostigmine Bromide Tablets contains lactose
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to use 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.

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
For myasthenia gravis:
- the usual adult dose is 1/2 to 2 tablets (30 to 120 mg Pyridostigmine Bromide 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 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 take them. The effect of each dose should last about four hours during the day and about 6 hours at night.

You should take Pyridostigmine Bromide Tablets so that they 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 Pyridostigmine Bromide Tablets) daily and for children 1/4 to 1 tablet (15 to 60 mg) daily, depending on the needs of the patient.

If you take more Pyridostigmine Bromide Tablets than you should
It is important you take this medicine as your doctor has told you. If you take too many tablets or someone else accidentally takes your tablets, contact your doctor or nearest hospital emergency department immediately.

If you forget to take Pyridostigmine Bromide Tablets
If you forget to take a dose, take it as soon as you remember, and take the next dose at the normal time. If it is almost time for your next dose, do not take a double dose to make up for forgotten tablets. If you miss more than a single dose, contact your doctor for advice.

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

4. Possible side effects

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

Possible side effects with Pyridostigmine Bromide Tablets:
Side effects of unknown frequency:
- sensitivity to the medicinal product,
- temporary loss of consciousness,
- hypotension, flushing,
- blurred vision,
- visual disturbances, producing more tears than usual,
- an irregular heartbeat, heart block, low blood pressure, fainting
- producing more phlegm than usual combined with constriction of the airways,
- feeling sick, vomiting, diarrhoea, stomach discomfort pain and cramps, producing more saliva than usual,
- rash,
- excessive sweating,
- muscle weakness and twitching, shaking, muscle cramps,
- sudden need to urinate.

If you are concerned about any of these effects talk to your doctor or pharmacist.

Reporting of side effects:
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Pyridostigmine Bromide 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 bottle label and on the carton. 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 to protect from moisture and light.

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.

6. Contents of the pack and other information

What Pyridostigmine Bromide Tablets contain
- the active substance is pyridostigmine bromide. Each tablet contains 60 mg of pyridostigmine bromide
- the other ingredients are lactose, colloidal silica and stearic acid.

What Pyridostigmine Bromide Tablets looks like and contents of the pack
Pyridostigmine Bromide Tablets are white to off-white round tablets of 9.6 mm diameter, scored with C 60 on one side and cross scoring on the other side.

Pyridostigmine Bromide Tablets are supplied in an HDPE plastic bottle with a child resistant cap containing a silica gel desiccant and cotton wool wad. Each bottle contains 200 tablets.

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This leaflet was last revised in February 2024.

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