PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRYDOSTRIN 60 mg sugar coated tablets

Pyridostigmine bromide

Contains sugar: Lactose monohydrate 120 mg per tablet

Read all of this leaflet carefully before you start taking PRYDOSTRIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PRYDOSTRIN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What PRYDOSTRIN is and what it is used for

PRYDOSTRIN contains pyridostigmine bromide as the active ingredient which 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.

PRYDOSTRIN 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.

2. What you need to know before you take PRYDOSTRIN

Do not take PRYDOSTRIN:

- If you are hypersensitive (allergic) to pyridostigmine bromide or any of the other ingredients of PRYDOSTRIN (listed in section 6).
- If you are constipated or cannot urinate, unless your doctor has told you to use this medicine.

Warnings and precautions

Take special care with PRYDOSTRIN:

- If you suffer from asthma or have other chest problems such as wheeziness, difficulty in breathing or chronic cough.
- If you have recently had coronary obstruction (heart attack), have a slow heartbeat or any other heart condition.
- If you have low blood pressure.
- If you have a stomach ulcer.
- If you have epilepsy.
- If you have Parkinson’s disease.

- If you have kidney problems.
- If you 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)
- If you have an overactive thyroid gland.

PRYDOSTRIN should be used with caution in elderly patients.

Other medicines and PRYDOSTRIN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 heartbeat.
- Other medicines that interfere with transmission between nerves and muscles.

If you are going to have surgery tell your doctor that you are taking PRYDOSTRIN. PRYDOSTRIN can stop the effect of some medicines used to relax muscles during surgery (e.g. pancuronium, vencuronium).

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The safety of PRYDOSTRIN during pregnancy and breastfeeding has not been established.

Driving and using machines

PRYDOSTRIN 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.

PRYDOSTRIN contains lactose

PRYDOSTRIN 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 PRYDOSTRIN.

3. How to take PRYDOSTRIN

Do not share medicines prescribed for you with any other person.

Always take PRYDOSTRIN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

For myasthenia gravis:

- The usual adult dose is 1 to 3 tablets (60 to 180 mg PRYDOSTRIN) to be taken two to four times daily, or higher doses if needed, as recommended by your doctor.
- Children: 7 mg/kg body-mass daily at four hourly intervals.

It is important to remember that the dosage must be individually titrated.

- No response to a specific dosage could be due to underdosage or overdosage.
- Usually in the case of too large a dose given too frequently, side effects of the muscarinic and/or nicotinic type will manifest (see section 4' Possible side effects').

Your doctor will tell you how long your treatment with PRYDOSTRIN will last. If you have the impression that the effect of PRYDOSTRIN is too strong or too weak, tell your doctor or pharmacist.

If you take more PRYDOSTRIN than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take PRYDOSTRIN

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

PRYDOSTRIN can have side effects.

Not all side effects reported for PRYDOSTRIN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRYDOSTRIN , please consult your health care provider for advice.

If any of the following happens, stop taking PRYDOSTRIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PRYDOSTRIN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent

- rash.

Frequency unknown

- visual disturbance, blurred vision, 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 cramps, producing more saliva than usual;
- excessive sweating;
- muscle weakness and twitching, shaking, muscle cramps;
- sudden, compelling urge to urinate.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of PRYDOSTRIN.

5. How to store PRYDOSTRIN

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Store in the original package in order to protect from moisture.
- Do not use after the expiry date stated on the label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PRYDOSTRIN contains

- The active substance is pyridostigmine bromide.

  Each tablet contains 60 mg of the dimethylcarbamic-ester of 1-methyl-3-hydroxypyridinium bromide (pyridostigmine bromide).

  The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, povidone, pregelatinized starch and talc, Opadry SGR 230U190010 translucent (glyceryl monostearate, hypromellose, macrogol/PEG, medium chain triglycerides, sucrose, talc) and Opadry SGR 231U25004 red (hypromellose, iron oxide red, iron oxide yellow, macrogol/PEG, medium chain triglycerides, polyvinyl alcohol, sucrose, talc, titanium dioxide)

What PRYDOSTRIN looks like and contents of the pack

PRYDOSTRIN tablets are reddish brown round biconvex sugar-coated tablets plain from both sides.

PRYDOSTRIN is packed in heat sealed ALU/ALU blisters, each containing 10 tablets packed in a carboard box.

Pack size: 150 tablets.

or

White, opaque HDPE bottles, 38 mm neck, with white, opaque polypropylene child-resistant closure, packed in a cardboard box.

Pack size: 150 tablets.

Holder of Certificate of Registration

Juno Pharma SA (Pty) Ltd

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This leaflet was last revised in

To follow

Registration number

580230

Access to the corresponding Professional Information

Website Address: www.trinitypharma.co.za