NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Pyridostigmine Bromide JAMP 60 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 60 mg pyridostigmine bromide.

Excipients with known effect: Lactose

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Pyridostigmine Bromide JAMP tablets are white, round and biplane tablets debossed with PB60 on one side and cross scored on another side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Myasthenia gravis, paralytic ileus, and postoperative urinary retention.

4.2 Dose and method of administration

Pyridostigmine Bromide JAMP tablets are for oral administration. Pyridostigmine Bromide JAMP has a gradual onset of effect (generally 30- 60 minutes).

Myasthenia Gravis

Adults

Doses of 30 to 120 mg by mouth are given at intervals throughout the day when maximum strength is needed (for example on rising and before meal times). The usual duration of action of a dose is three to four hours in the daytime but a longer effect (six hours) is often obtained with a dose taken on retiring for bed.

The total daily dose is usually in the range of 5-20 tablets but some patients may require doses higher than these.

Paediatric Population

Children under 6 years old should receive an initial dose of half a tablet (30 mg) of Pyridostigmine Bromide JAMP. Children 6-12 years old should receive one tablet (60 mg). Dosage should be increased gradually, in increments of 15-30 mg daily, until maximum improvement is obtained. Total daily requirements are usually in the range of 30-360 mg by mouth.

Newborn Infants

Neostigmine has generally been preferred in the treatment of neonatal myasthenia. However, Pyridostigmine Bromide JAMP can be given, particularly if neostigmine proves unsuitable on account of pronounced cholinergic effects.

The dosage requirements of Pyridostigmine Bromide JAMP range from 5-10 mg orally every four hours, given 30-60 minutes before feeding. Treatment is not usually required beyond eight weeks of age except in the rare conditions of congenital and familial infantile myasthenia.

Other indications (paralytic ileus, post-operative urinary retention)

Adults

The usual dose is 1 to 4 tablets by mouth.

Children

The dosage is 15 to 60 mg per day by mouth.

The frequency of these doses may be varied according to the needs of the patient.

Special Populations

Elderly

There are no specific dosage recommendations for Pyridostigmine Bromide JAMP in elderly patients.

Renal impairment

Pyridostigmine bromide is mainly excreted unchanged by the kidney, therefore lower doses may be required in patients with renal disease and treatment should be based on titration of drug dosage to effect.

Hepatic impairment

There are no specific dosage recommendations for Pyridostigmine Bromide JAMP in patients with hepatic impairment.

4.3 Contraindications

Pyridostigmine Bromide JAMP is contraindicated in patients with:

- Known hypersensitivity to the active substance, bromides or to any of its excipients listed in section 6.1.
- Mechanical gastrointestinal or urinary obstruction.

Pyridostigmine Bromide JAMP should not be used in conjunction with depolarising muscle relaxants such as suxamethonium as neuromuscular blockade may be potentiated and prolonged apnoea may result.

4.4 Special warnings and precautions for use

Hypersensitivity reactions may occur in susceptible individuals.

Extreme caution is required when administering Pyridostigmine Bromide JAMP to patients with bronchial asthma.

Care should be taken in patients with:

- Bradycardia
- Recent coronary occlusion
- Hypotension
- Vagotonia
- Epilepsy or Parkinsonism.

There is no evidence to suggest that pyridostigmine bromide has any special effects in the elderly. However, elderly patients may be more susceptible to dysrhythmias than the younger adult.

Pyridostigmine bromide is mainly excreted unchanged by the kidney, therefore lower doses may be required in patients with renal disease and treatment should be based on titration of drug dosage to effect.

Pyridostigmine Bromide JAMP should not be given during cyclopropane or halothane anaesthesia; however, it may be used after withdrawal of these agents.

The requirement of pyridostigmine bromide is usually markedly decreased after thymectomy or when additional therapy (steroids, immunosuppressant medicines) is given.

When relatively large doses of Pyridostigmine Bromide JAMP are taken by myasthenic patients it may be necessary to give atropine or other anticholinergic medicines to counteract the muscarinic effects. It should be noted that the slower gastrointestinal motility caused by these medicines may affect the absorption of oral pyridostigmine bromide.

In all patients the possibility of 'cholinergic crisis' due to overdosage of Pyridostigmine Bromide JAMP, and differentiation from 'myasthenic crisis' due to increased severity of the disease, must be borne in mind. Both types of crisis are manifested by increased muscle weakness, but whereas myasthenic crisis may require more intensive anticholinesterase treatment, cholinergic crisis calls for immediate discontinuation of this treatment and institution of appropriate supportive measure, including respiratory assistance.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Immunosuppressant drugs

The requirement for pyridostigmine bromide could be decreased when additional therapy (steroids, immunosuppressant drugs) is given although peak plasma concentration and AUC of pyridostigmine may decrease by high doses of corticosteroids.

Antimuscarinics

Atropine and hyoscine antagonise the muscarinic effects of pyridostigmine bromide.

Muscle relaxants

Pyridostigmine antagonises the effect of non-depolarising muscle relaxants (e.g. pancuronium and vecuronium). Pyridostigmine may prolong the effect of depolarising muscle relaxants (e.g. suxamethonium).

4.6 Fertility, pregnancy and lactation

Pregnancy

Category C

The safety of pyridostigmine bromide during pregnancy or lactation has not been established.

The maternal requirement for this medicine in the context of myasthenia gravis may be absolute. Cholinergic effects in the neonate are rare.

Although the possible hazards to mother and child must be weighed against the potential benefits in every case, experience with pyridostigmine bromide in pregnant patients with myasthenia gravis has revealed no untoward effect of the medicine on the course of pregnancy.

As the severity of myasthenia gravis often fluctuates considerably, particular care is required to avoid cholinergic crises due to overdosage of the medicine, but otherwise management is no different from that in non-pregnant patients.

Lactation

Observations indicated that only negligible amounts of pyridostigmine bromide are secreted in breast milk; nevertheless, due regard should be paid to possible effects on the breast-feeding infant.

4.7 Effects on ability to drive and use machines

Due to miosis and accommodation disorders caused by pyridostigmine bromide or an inadequate treatment of myasthenia gravis, Pyridostigmine Bromide JAMP may impair visual acuity and consequently the ability to react as well as the ability to drive and use machines.

4.8 Undesirable effects

As with all cholinergic products, Pyridostigmine Bromide JAMP may have unwanted functional effects on the autonomic system. Muscarine-like adverse effects may be exhibited as nausea, vomiting, diarrhoea, abdominal cramps, increased peristaltic and increased bronchial secretion, salivation, bradycardia and miosis.

The primary nicotinic effects are muscle spasms, fasciculation and muscular weakness.

Adverse reactions are listed below according to system organ class and frequency. Frequencies are defined according to the following convention:

Very Common (≥1/10), Common (≥1/100 to <1/100), Uncommon (≥1/1000 to < 1/100), Rare (≥1/10,000 to <1/1000), Very rare (<1/10,000), Not known (cannot be estimated from the available data).

Eye disorders

Frequency not known: Miosis, increased lacrimation, accommodation disorders.

Cardiac disorders

Frequency not known: Arrhythmia (including bradycardia, tachycardia, AV block), as well as syncope and hypotension (see section 4.9).

Respiratory, thoracic and mediastinal disorders

Frequency not known: Increased bronchial secretion combined with bronchoconstriction.

Gastrointestinal disorders

Frequency not known: Nausea, vomiting, diarrhoea, abdominal cramps, gastrointestinal hypermotility, salivary hypersecretion.

Skin and subcutaneous tissue disorders

Frequency not known: Rash (disappears usually soon after ceasing of the medicine. Bromide containing medicines should no longer be used.), hyperhydrosis.

Musculoskeletal and connective tissue disorders

Frequency not known: Increased muscle weakness, fasciculation, tremors and muscle cramps or muscle hypotonia (see section 4.9).

Renal and urinary disorders

Frequency not known: Urinary urgency

Because these symptoms may be an indication of cholinergic crisis, the physician should be notified immediately to clarify the diagnosis (see section 4.9).

Reporting of suspected reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

Signs of overdosage due to muscarinic effects may include abdominal cramps, increased peristalsis, diarrhoea, nausea and vomiting, increased bronchial secretions, salivation, diaphoresis and miosis.

Nicotinic effects consist of muscular cramps, fasciculation and general weakness. Bradycardia and hypotension may also occur.

Artificial ventilation should be instituted if respiration is severely depressed. Atropine sulphate 1 to 2 mg intravenously is an antidote to the muscarinic effects.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharamcotherapeutic group: Nervous system, parasympathomimetics, anticholinesterases, pyridostigmine. ATC Code: N07AA02.

Pyridostigmine bromide is an antagonist to cholinesterase, the enzyme that normally destroys acetylcholine. Pyridostigmine Bromide JAMP can briefly be described, therefore, as the potentiation of naturally occurring acetylcholine. Pyridostigmine bromide has a more prolonged action than neostigmine although it is somewhat slower to take effect (generally taking 30-60 minutes). Because it has a weaker 'muscarinic' action than neostigmine, it is usually much better tolerated by myasthenic patients in whom the longer action is also an advantage.

5.2 Pharmacokinetic properties

Oral pyridostigmine is poorly absorbed. Maximum plasma concentrations occur at 1 to 2 hours and it is eliminated by the kidney largely unchanged with a half-life of 3 to 4 hours.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the datasheet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silica
Anhydrous lactose
Stearic acid

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25°C. Protect from light. Protect from moisture.
Keep in a dry place, in a well-closed container with the desiccant enclosed.

6.5 Nature and contents of container

HDPE bottle, polypropylene CT Closure with induction sealing liner.
Pack size: 100 tablets

6.6 Special precautions for disposal

No special requirements.

7. MEDICINE SCHEDULE

Prescription

8. SPONSOR

JAMP Pharma New Zealand Limited
Floor 7, 36 Brandon Street
Wellington 6011
New Zealand

Toll-free number: 0800 600 530

9. DATE OF FIRST APPROVAL

30/06/2026

10. DATE OF REVISION OF THE TEXT

30/06/2026

SUMMARY TABLE OF CHANGES

Date	Changes
NA	New Document