

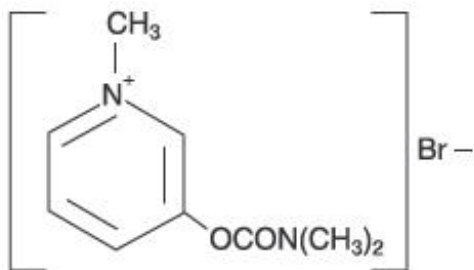
## **PYRIDOSTIGMINE BROMIDE- pyridostigmine bromide tablet AvPAK**

### **Pyridostigmine Bromide Tablets, USP**

**Rx only**

#### **DESCRIPTION**

Pyridostigmine Bromide Tablets, USP is an orally active cholinesterase inhibitor. Chemically, pyridostigmine bromide is 3-hydroxy-1-methylpyridinium bromide dimethylcarbamate. Its structural formula is:



Pyridostigmine bromide is available as tablets containing 60 mg pyridostigmine bromide; each tablet also contains lactose, silicon dioxide and stearic acid.

#### **CLINICAL PHARMACOLOGY**

Pyridostigmine bromide inhibits the destruction of acetylcholine by cholinesterase and thereby permits freer transmission of nerve impulses across the neuromuscular junction. Pyridostigmine is an analog of neostigmine (Prostigmin), but differs from it in certain clinically significant respects; for example, pyridostigmine is characterized by a longer duration of action and fewer gastrointestinal side effects.

#### **INDICATIONS AND USAGE**

Pyridostigmine Bromide Tablets are useful in the treatment of myasthenia gravis.

#### **CONTRAINDICATIONS**

Pyridostigmine Bromide Tablets are contraindicated in mechanical intestinal or urinary obstruction, and particular caution should be used in its administration to patients with bronchial asthma. Care should be observed in the use of atropine for counteracting side effects, as discussed below.

#### **WARNINGS**

Although failure of patients to show clinical improvement may reflect underdosage, it can also be indicative of overdosage. As is true of all cholinergic drugs, overdosage of Pyridostigmine Bromide Tablets may result in cholinergic crisis, a state characterized by increasing muscle weakness which, through involvement of the muscles of respiration, may lead to death. Myasthenic crisis due to an increase in the severity of the disease is also accompanied by extreme muscle weakness, and thus may be difficult to distinguish from cholinergic crisis on a symptomatic basis. Such differentiation is

extremely important, since increases in doses of Pyridostigmine Bromide Tablets or other drugs of this class in the presence of cholinergic crisis or of a refractory or "insensitive" state could have grave consequences. Osserman and Genkins<sup>1</sup> indicate that the differential diagnosis of the two types of crisis may require the use of Tensilon (edrophonium chloride) as well as clinical judgment. The treatment of the two conditions obviously differs radically. Whereas the presence of myasthenic crisis suggests the need for more intensive anticholinesterase therapy, the diagnosis of cholinergic crisis, according to Osserman and Genkins,<sup>1</sup> calls for the prompt *withdrawal* of all drugs of this type. The immediate use of atropine in cholinergic crisis is also recommended.

Atropine may also be used to abolish or obtund gastrointestinal side effects or other muscarinic reactions; but such use, by masking signs of overdosage, can lead to inadvertent induction of cholinergic crisis.

For detailed information on the management of patients with myasthenia gravis, the physician is referred to one of the excellent reviews such as those by Osserman and Genkins,<sup>2</sup> Grob<sup>3</sup> or Schwab.<sup>4,5</sup>

### **Usage in Pregnancy**

The safety of Pyridostigmine Bromide Tablets during pregnancy or lactation in humans has not been established. Therefore, use of Pyridostigmine Bromide Tablets in women who may become pregnant requires weighing the drug's potential benefits against its possible hazards to mother and child.

### **PRECAUTIONS**

Pyridostigmine is mainly excreted unchanged by the kidney.<sup>6,7,8</sup> Therefore, lower doses may be required in patients with renal disease, and treatment should be based on titration of drug dosage to effect.<sup>6,7</sup>

### **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

### **ADVERSE REACTIONS**

The side effects of Pyridostigmine Bromide Tablets are most commonly related to overdosage and generally are of two varieties, muscarinic and nicotinic. Among those in the former group are nausea, vomiting, diarrhea, abdominal cramps, increased peristalsis, increased salivation, increased bronchial secretions, miosis and diaphoresis. Nicotinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness. Muscarinic side effects can usually be counteracted by atropine, but for reasons shown in the preceding section the expedient is not without danger. As with any compound containing the bromide radical, a skin rash may be seen in an occasional patient. Such reactions usually subside promptly upon discontinuance of the medication.

**To report SUSPECTED ADVERSE REACTIONS, contact AvKARE, Inc. at 1-855-361-3993 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

### **DOSAGE AND ADMINISTRATION**

Pyridostigmine Bromide Tablets contain 60 mg pyridostigmine bromide each.

#### **Dosage**

The size and frequency of the dosage must be adjusted to the needs of the individual patient.

The average dose is ten 60 mg tablets daily spaced to provide maximum relief when maximum strength is needed. In severe cases as many as 25 tablets a day may be required, while in mild cases one to six tablets a day may suffice.

**NOTE:**For Information on a diagnostic test for myasthenia gravis, and for the evaluation and stabilization of therapy, please see product literature on Tensilon (edrophonium chloride).

## **HOW SUPPLIED**

Pyridostigmine Bromide Tablets, USP are available containing 60 mg of pyridostigmine bromide supplied in unit dose packaging. NDC 50268-638-15 (10 tablets per card, 5 cards per carton). Each tablet is cross-scored on one side and engraved "OCEANSIDE 302" on the other side.

Store Pyridostigmine Bromide Tablets at 25°C (77°F); excursions permitted to 15° - 30°C (59°-86°F). Keep Pyridostigmine Bromide Tablets in a dry place.

Dispensed in Unit Dose Package. For Institutional Use Only.

## **REFERENCES**

1. Osserman KE, Genkins G. Studies in myasthenia gravis: Reduction in mortality rate after crisis. *JAMA*. Jan 1963; 183:97-101.
2. Osserman KE, Genkins G. Studies in myasthenia gravis. *NY State J Med*. June 1961; 61:2076-2085.
3. Grob D. Myasthenia gravis. A review of pathogenesis and treatment. *Arch Intern Med*. Oct 1961; 108:615-638.
4. Schwab RS. Management of myasthenia gravis. *New Eng J Med*. Mar 1963; 268:596-597.
5. Schwab RS. Management of myasthenia gravis. *New Eng J Med*. Mar 1963; 268:717-719.
6. Cronnelly R, Stanski DR, Miller RD, Sheiner LB. Pyridostigmine kinetics with and without renal function. *Clin Pharmacol Ther*. 1980; 28: No. 1, 78-81.
7. Miller RD. Pharmacodynamics and pharmacokinetics of anticholinesterase. In: Ruegheimer E, Zindler M, ed. *Anesthesiology*. (Hamburg, Germany: Congress; Sep 14-21,1980; 222-223.) (Int Congr. No. 538), Amsterdam, Netherlands: Excerpta Medica; 1981.
8. Breyer-Pfaff U, Maier U, Brinkmann AM, Schumm F. Pyridostigmine kinetics in healthy subjects and patients with myasthenia gravis. *Clin Pharmacol Ther*. 1985; 5:495-501.

## **Manufactured for:**

**AvKARE, Inc.**

**Pulaski, TN 38478**

**Mfg. Rev. 08/16**

**AV 08/19 (P)**

**AvPAK**

**PRINCIPAL DISPLAY PANEL - 100 Tablets Bottle Label**

NDC 50268-638-15

# Pyridostigmine Bromide Tablets, USP

60 mg

Rx Only

50 Tablets (5 x 10) Unit Dose



NDC 50268-638-15

# Pyridostigmine Bromide Tablets, USP

60 mg

Rx Only

50 Tablets (5 x 10) Unit Dose



Each tablet contains 60 mg pyridostigmine bromide.

**IMPORTANT:** These tablets are hygroscopic.

Keep in dry place.

Usual dosage: See accompanying package insert.

Store at 25°C (77°F). excursions permitted to 15° - 30°C (59° - 86°F).

Keep this and all medication out of the reach of children.

Manufactured for:  
AvKARE Inc.  
Pulaski, TN 38478



Mfg. Rev. 08/16

AV 08/19 (P)

## PYRIDOSTIGMINE BROMIDE

pyridostigmine bromide tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:50268-638(NDC:68682-302)
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOSTIGMINE BROMIDE (UNII: KVI301NA53) (PYRIDOSTIGMINE - UNII:19QM69HH21)	PYRIDOSTIGMINE BROMIDE	60 mg

### Inactive Ingredients

Ingredient Name	Strength
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	4 pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	OCEANSIDE;302
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-638-15	50 in 1 BOX; Type 0: Not a Combination Product	08/26/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA009829	08/26/2019	

**Labeler** - AvPAK (832926666)

Revised: 8/2019

AvPAK