PYRIDOSTIGMINE BROMIDE- pyridostigmine bromide tablet
American Health Packaging

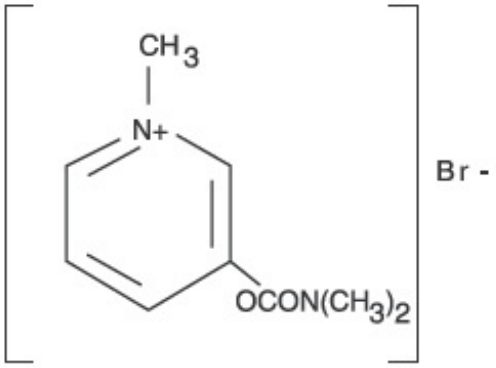
Pyridostigmine Bromide Tablets USP

8249401/0916

Rx only

DESCRIPTION

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



$C_9H_{13}BrN_2O_2$
Mol. Wt.: 261.12

Pyridostigmine bromide tablets USP is available as a 60 mg tablet for oral administration. The tablet contains the following inactive ingredients: colloidal silicon dioxide, lactose anhydrous, magnesium stearate 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 is useful in the treatment of myasthenia gravis.

CONTRAINDICATIONS

Pyridostigmine bromide is 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 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 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 [1] 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, [1] 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, [2] Grob [3] or Schwab. [4,5]

PRECAUTIONS

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

Pregnancy

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

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

The side effects of pyridostigmine bromide 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.

DOSAGE AND ADMINISTRATION

Pyridostigmine bromide is available in tablets, each containing 60 mg pyridostigmine bromide.

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, 60 mg - Each white to off white, round, flat-faced tablet is debossed with "G3511" on one side and quadrisect on the other side.

Unit dose packages of 100 (10 x 10) NDC 68084-494-01

IMPORTANT: These tablets are hygroscopic. Keep in a dry place.

Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

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. *Anaesthesiology*. (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.

FOR YOUR PROTECTION: Do not use if blister is torn or broken.

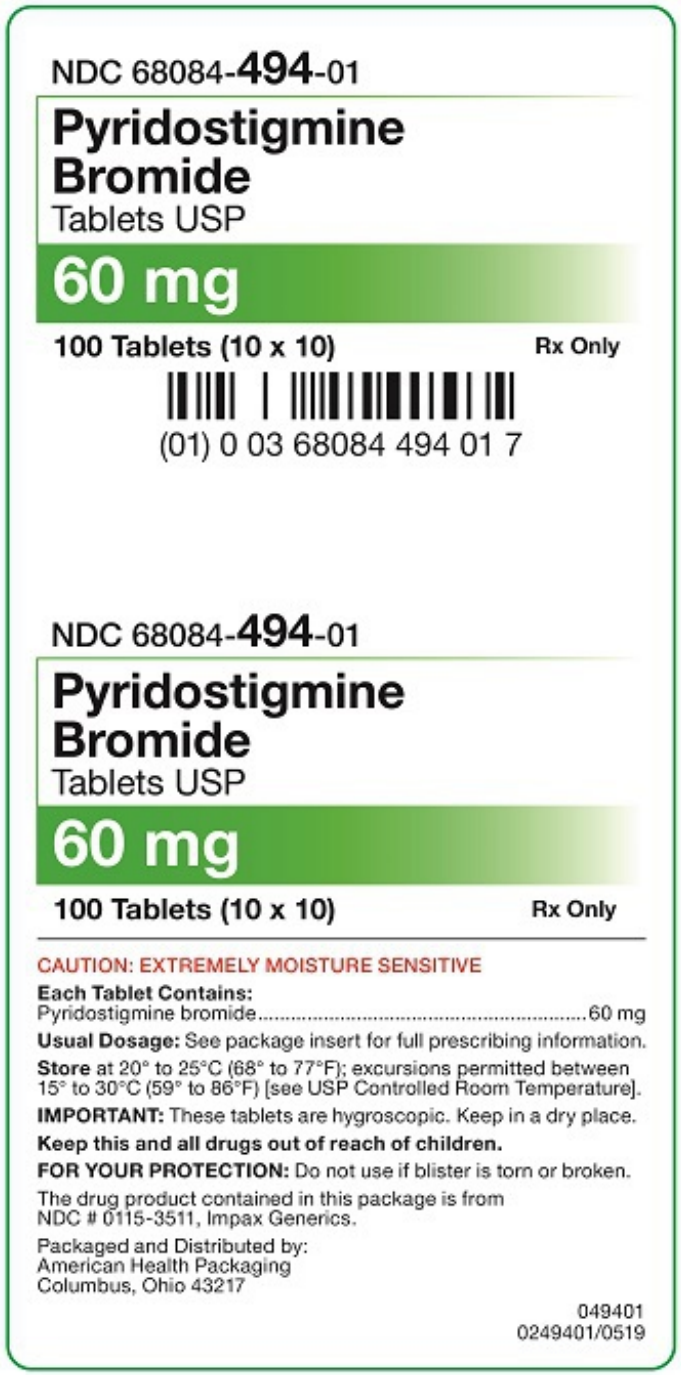
PACKAGING INFORMATION

American Health Packaging unit dose blisters (see How Supplied section) contain drug product from Impax Generics as follows:
(60 mg / 100 UD) NDC 68084-494-01 packaged from NDC 0115-3511

Distributed by:
American Health Packaging
Columbus, OH 43217

8249401/0916

Package/Label Display Panel — Carton — 60 mg



NDC 68084- **494**-01
Pyridostigmine
Bromide
Tablets USP
60 mg

100 Tablets (10 x 10) □□□□□ □□□□□ □□□□ **Rx Only**

CAUTION: EXTREMELY MOISTURE SENSITIVE

Each Tablet Contains:
Pyridostigmine bromide.....60 mg

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

IMPORTANT: These tablets are hygroscopic. Keep in a dry place.

Keep this and all drugs out of reach of children.

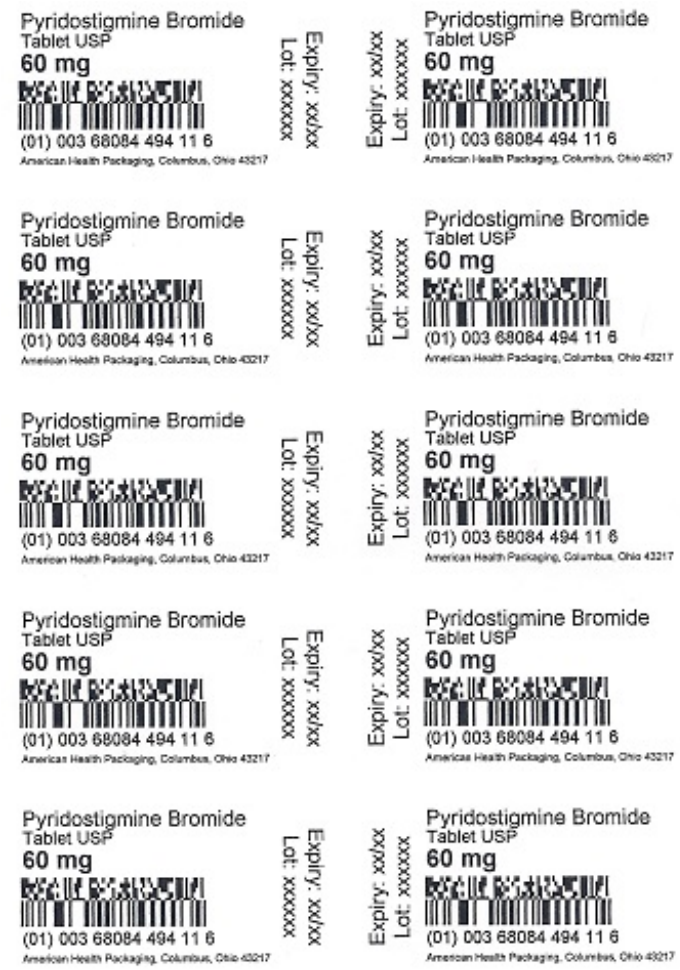
FOR YOUR PROTECTION: Do not use if blister is torn or broken.

The drug product contained in this package is from
NDC # 0115-3511, Impax Generics.

Distributed by:
American Health Packaging
Columbus, Ohio 43217

049401
0249401/0519

Package/Label Display Panel — Blister — 60 mg



Pyridostigmine Bromide
Tablet USP
60 mg

PYRIDOSTIGMINE BROMIDE			
pyridostigmine bromide tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68084-494(NDC:0115-3511)

Route of Administration	ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

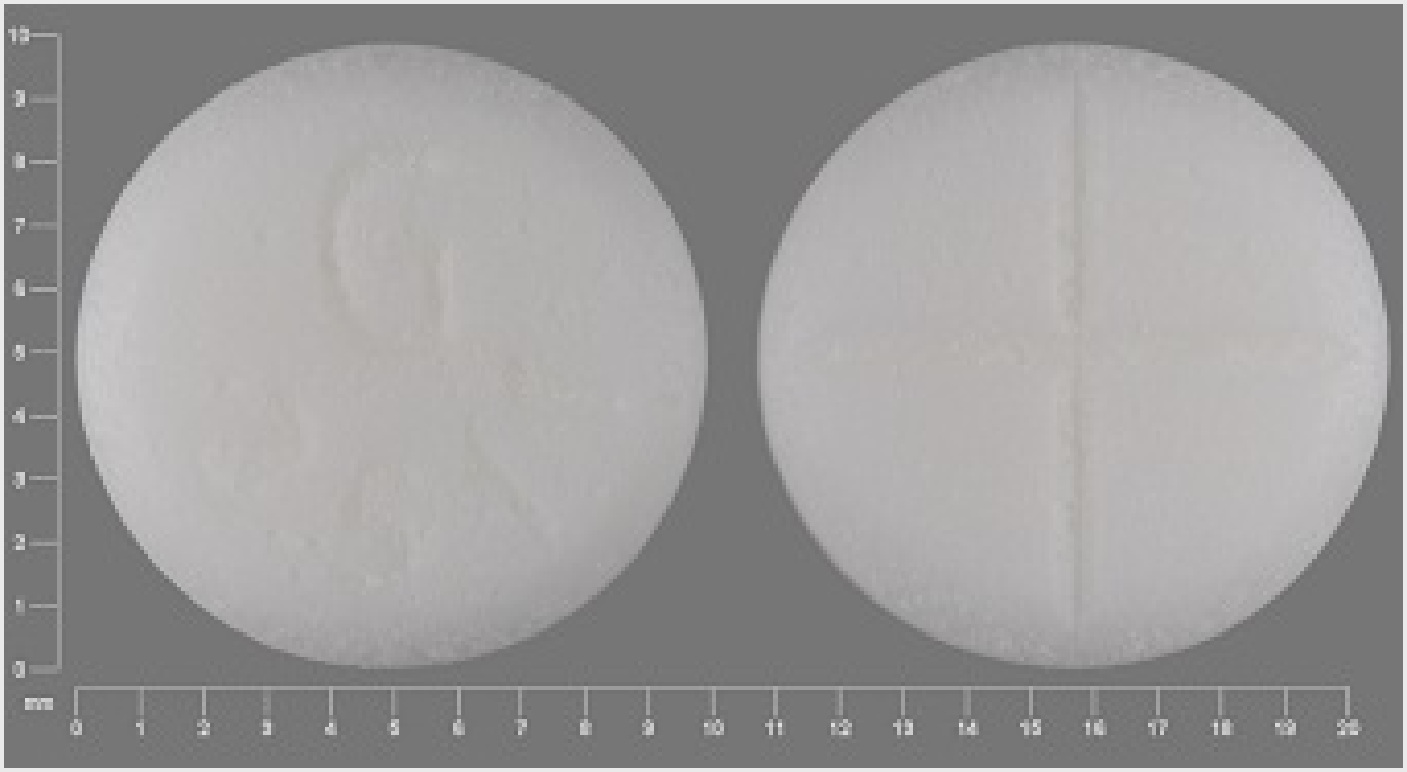
Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (white to off white)	**Score**	4 pieces
Shape	ROUND (flat-faced)	**Size**	10mm
Flavor		**Imprint Code**	G3511
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68084-494-01	100 in 1 BOX, UNIT-DOSE	09/27/2011	
1	NDC:68084-494-11	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040502	09/27/2011	

Labeler - American Health Packaging (929561009)

Establishment

Name	Address	ID/FEI	Business Operations
American Health Packaging		929561009	repack(68084-494)

Revised: 7/2019 American Health Packaging