

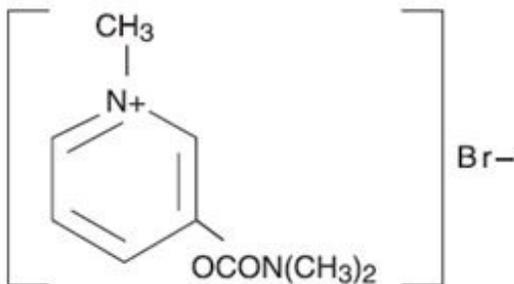
PYRIDOSTIGMINE BROMIDE- pyridostigmine bromide tablet, extended release
Amneal Pharmaceuticals of New York LLC

Pyridostigmine Bromide Extended-Release Tablets
(180 mg)

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:



Pyridostigmine bromide extended-release tablets are available as extended-release tablets containing 180 mg pyridostigmine bromide; each tablet also contains carnauba wax, copovidone, lactose, magnesium stearate, and silicon dioxide.

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, 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 Genkins¹ indicate that the differential diagnosis of the two types of crisis may require the use of 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 Genkins¹, 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 Genkins², Grob³ or Schwab^{4,5}.

Usage in 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.

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}.

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.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

Pyridostigmine bromide is available in extended-release dosage form:

Extended-Release Tablets — each containing 180 mg pyridostigmine bromide. This form provides uniformly slow release, hence prolonged duration of drug action; it facilitates control of myasthenic symptoms with fewer individual doses daily. The immediate effect of a 180 mg extended-release tablet is about equal to that of a 60 mg immediate-release tablet; however, its duration of effectiveness, although varying in individual patients, averages 2_{1/2} times that of a 60 mg dose.

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

NDC 0115-1404-08

Pyridostigmine Bromide Extended-Release Tablets

180 mg

**CAUTION: EXTREMELY MOISTURE SENSITIVE.
DO NOT REMOVE DESICCANT. CLOSE TIGHTLY.**

Pharmacist: Dispense in this
unit-of-use container.



Each tablet contains 180 mg of pyridostigmine bromide.

USUAL DOSAGE: See package insert for full prescribing information.

**IMPORTANT: THESE TABLETS ARE HYGROSCOPIC.
KEEP IN A DRY PLACE WITH THE SILICA GEL ENCLOSED.**

Dispense in tightly-closed, light-resistant container as defined in the USP, with child-resistant closure, as required.

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

Do not use if printed safety seal under cap is broken or missing.

Keep this and all medication out of reach of children.

Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Rev. 01-2019-00



Non-Varnish Area
(For Lot And Exp. Date)
0.875 x 1.5 inch

PYRIDOSTIGMINE BROMIDE

pyridostigmine bromide tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0115-1404
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOSTIGMINE BROMIDE (UNII: KVI301NA53) (PYRIDOSTIGMINE - UNII:19QM69HH21)	PYRIDOSTIGMINE BROMIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW (light brown to pale yellow)	Score	2 pieces
Shape	OVAL (capsule-shaped)	Size	19mm
Flavor		Imprint Code	W1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0115-1404-08	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/18/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203184	09/18/2015	

Labeler - Amneal Pharmaceuticals of New York LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals of New York, LLC		123797875	ANALYSIS(0115-1404) , MANUFACTURE(0115-1404)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals, LLC		969951594	PACK(0115-1404)

Revised: 1/2019

Amneal Pharmaceuticals of New York LLC