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](attachment:image)

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

ACTIONS:

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.

INDICATION

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\(^1\) 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.\(^4,5\)

**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.

**PRECAUTION**

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 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 Oceanside Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or 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 each in bottles of 100 (NDC 68682-302-10). 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 15º to 30°C (59º to 86°F). Keep Pyridostigmine Bromide Tablets in a dry place with the silica gel enclosed.

REFERENCES


Distributed by:
Oceanside Pharmaceuticals, a division of Bausch Health US, LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Bausch Health Companies Inc.
Laval, Quebec H7L 4A8, Canada

© 2020 Bausch Health Companies Inc. or its affiliates

Rev. April 2020
9549801
50104246C

PRINCIPAL DISPLAY PANEL - 100 Tablets Bottle Label

NDC 68682-302-10

Rx only

Pyridostigmine Bromide Tablets, USP

60 mg
# PYRIDOSTIGMINE BROMIDE

pyridostigmine bromide tablet

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item Code (Source)</td>
<td>NDC:68682-302</td>
</tr>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pyridostigmine Bromide (UNII: KV3B01NA53) (Pyridostigmine - UNII:19QM69HH21)</td>
<td>Pyridostigmine Bromide</td>
<td>60 mg</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)</td>
<td></td>
</tr>
<tr>
<td>silicon dioxide (UNII: ETJ7Z6XBU4)</td>
<td></td>
</tr>
<tr>
<td>stearic acid (UNII: 4ELV7Z65AP)</td>
<td></td>
</tr>
</tbody>
</table>
### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>WHITE</th>
<th>Score</th>
<th>4 pieces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>ROUND</td>
<td>Size</td>
<td>10mm</td>
</tr>
<tr>
<td>Flavor</td>
<td></td>
<td>Imprint Code</td>
<td>OCEANSIDE;302</td>
</tr>
<tr>
<td>Contains</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:68682-302-10</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>10/30/2007</td>
<td></td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA authorized generic</td>
<td>NDA009829</td>
<td>10/30/2007</td>
<td></td>
</tr>
</tbody>
</table>

### Labeler - Oceanside Pharmaceuticals (832011691)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bausch Health Companies Inc.</td>
<td></td>
<td>245141858</td>
<td>MANUFACTURE(68682-302)</td>
</tr>
</tbody>
</table>

Revised: 4/2020