METHSCOPOLAMINE BROMIDE- methscopolamine bromide tablet
BAYSHORE PHARMACEUTICALS LLC

Methscopolamine Bromide Tablets, USP 2.5 mg and 5 mg
Bayshore Pharmaceuticals LLC

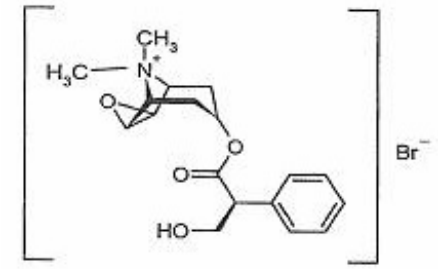
Rx Only

DESCRIPTION

Methscopolamine Bromide Tablets, USP 2.5 mg and 5 mg contain methscopolamine bromide USP, an anticholinergic, which occurs as white crystals, or as a white odorless crystalline powder. Methscopolamine bromide melts at about 225°C with decomposition. The drug is freely soluble in water, slightly soluble in alcohol, and insoluble in acetone and in chloroform.

The chemical name for methscopolamine bromide is 3-Oxa-9-azoniatricyclo [3.3.1.$0^{2,4}$]nonane, 7-(3-hydroxy-1-oxo-2-phenylpropoxy)-9, 9-dimethyl-, bromide, [7(s)-(1α, 2β, 4β, 5α, 7β)]- and the molecular weight is 398.30.

The structural formula is represented below:



Methscopolamine Bromide Tablets, USP 2.5 mg for oral administration contain 2.5 mg of methscopolamine bromide USP. Methscopolamine Bromide Tablets, USP 5 mg for oral administration contain 5 mg of methscopolamine bromide USP.

Inactive ingredients: microcrystalline cellulose NF, pregelatinized starch NF, colloidal silicon dioxide

NF, magnesium stearate NF.

Contains no lactose.

CLINICAL PHARMACOLOGY

Methscopolamine bromide is an anticholinergic agent which possesses most of the pharmacologic actions of that drug class. These include reduction in volume and total acid content of gastric secretion, inhibition of gastrointestinal motility, inhibition of salivary excretion, dilation of the pupil and inhibition of accommodation with resulting blurring of vision. Large doses may result in tachycardia.

PHARMACOKINETICS

Methscopolamine bromide is a quaternary ammonium derivative of scopolamine. As a class, these agents are poorly and unreliably absorbed.[1, 2] Total absorption of quaternary ammonium derivatives of the alkaloids is 10 to 25%. Rate of absorption is not available. Quaternary ammonium salts have limited absorption from intact skin, and conjunctival penetration is poor.[1] Little is known of the fate and excretion of most of these agents.[1] Following oral administration, drug effects appear in about one hour and persist for 4 to 6 hours.[2] Methscopolamine bromide has limited ability to cross the blood-brain

barrier.[3,4,5] The drug is excreted primarily in the urine and bile, or as unabsorbed drug in feces.[2] There is no data on the presence of methscopolamine in breast milk; traces of atropine have been found after administration of atropine.[1]

INDICATIONS AND USAGE

Adjunctive therapy for the treatment of peptic ulcer.

METHSCOPOLAMINE BROMIDE HAS NOT BEEN SHOWN TO BE EFFECTIVE IN CONTRIBUTING TO THE HEALING OF PEPTIC ULCER, DECREASING THE RATE OF RECURRENCE OR PREVENTING COMPLICATIONS.

CONTRAINDICATIONS

Glaucoma; obstructive uropathy (e.g., bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (e.g., pyloroduodenal stenosis); paralytic ileus; intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis.

Methscopolamine Bromide Tablets, USP 2.5 mg and 5 mg is contraindicated in patients who are

hypersensitive to methscopolamine bromide or related drugs.

WARNINGS

In the presence of high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with drug use.

Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance treatment with this drug would be inappropriate and possibly harmful.

Methscopolamine bromide may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug.

With overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis.

PRECAUTIONS

1. General precautions

Use Methscopolamine Bromide Tablets, USP 2.5 mg and 5 mg with caution in the elderly and in all patients with: autonomic neuropathy; hepatic or renal disease; or ulcerative colitis –large doses may suppress intestinal motility to the point of producing a paralytic ileus and for this reason precipitate or aggravate "toxic megacolon," a serious complication of the disease.

The drug also should be used with caution in patients having hyperthyroidism, coronary heart disease, congestive heart failure, tachyarrhythmia, tachycardia, hypertension, or prostatic hypertrophy.

2. Information for patient

See statement under **WARNINGS.**

3. Laboratory tests

Progress of the peptic ulcer under treatment should be followed by upper gastrointestinal contrast

radiology or endoscopy to insure healing. Stool tests for occult blood and blood hemoglobin or hematocrit values should be followed to rule out bleeding from the ulcer.

4. Drug interactions

Additive anticholinergic effects may result from concomitant use with antipsychotics, tricyclic antidepressants, and other drugs with anticholinergic effects. Concomitant administration with antacids may interfere with the absorption of methscopolamine bromide.

5. Carcinogenesis, mutagenesis, impairment of fertility

No long-term studies in animals have been performed to evaluate carcinogenic potential.

6. Pregnancy

Teratogenic effects

Pregnancy Category C. Animal reproduction studies have not been conducted with methscopolamine bromide. It is also not known whether methscopolamine bromide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Methscopolamine bromide should be given to a pregnant woman only if clearly needed.

7. Nursing mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methscopolamine bromide is administered to a nursing woman.

Anticholinergic drugs may suppress lactation.

8. Pediatric use

Safety and efficacy in children have not been established.

ADVERSE REACTIONS

The following adverse reactions have been observed, but there is not enough data to support an estimate of frequency.

Cardiovascular: Tachycardia, palpitation.

Allergic: Severe allergic reaction or drug idiosyncrasies including anaphylaxis.

CNS: Headaches, nervousness, mental confusion, drowsiness, dizziness.

Special Senses: Blurred vision, dilation of the pupil, cycloplegia, increased ocular tension, loss of taste.

Renal: Urinary hesitancy and retention.

Gastrointestinal: Nausea, vomiting, constipation, bloated feeling.

Dermatologic: Decreased sweating, urticaria and other dermal manifestations.

Miscellaneous: Xerostomia, weakness, insomnia, impotence, suppression of lactation.

DRUG ABUSE AND DEPENDENCE

Not applicable.

OVERDOSAGE

The symptoms of overdosage with Methscopolamine Bromide Tablets, USP 2.5 mg and 5 mg progress

from intensification of the usual side effects to CNS disturbances (from restlessness and excitement to psychotic behavior), circulatory changes (flushing, fall in blood pressure, circulatory failure), respiratory failure, paralysis, and coma.

Measures to be taken are (1) induction of emesis and (2) injection of physostigmine 0.5 to 2 mg intravenously, and repeated as necessary up to a total of 5 mg. Fever may be treated symptomatically (alcohol sponging, ice packs). Excitement of a degree which demands attention may be managed with sodium thiopental 2% solution given slowly intravenously or chloral hydrate (100 to 200 mL of a 2% solution) by rectal infusion. In the event of progression of the curare-like effect to paralysis of the respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns.

The oral LD_{50} in rats is 1,352 to 2,617 mg/kg.

No data is available on the dialyzability of methscopolamine bromide.

DOSAGE AND ADMINISTRATION

The average dosage of Methscopolamine Bromide Tablets, USP is 2.5 mg one-half hour before meals and 2.5 to 5 mg at bedtime. A starting dose of 12.5 mg daily will be clinically effective in most patients without the production of appreciable side effects.

If the patient is experiencing symptoms such as severe abdominal pain or cramping which demand prompt relief, the drug may be started on a daily dosage of 20 mg, administered in doses of 5 mg one-half hour before meals and at bedtime. If very unpleasant side effects develop promptly, the daily dosage should be reduced. If neither symptomatic relief nor side effects appear, the daily dosage may be increased. Some patients have tolerated 30 mg daily with no unpleasant reactions.

Patients whose dosage has been reduced to eliminate or modify side effects often continue to show adequate response both subjectively in relief of symptoms and objectively as measured by antisecretory effects.

The ultimate aim of therapy is to arrive at a dosage which provides maximal clinical effectiveness with a minimum of unpleasant side effects. Many patients report no side effects on a dosage which gives complete relief of symptoms. On the other hand, some patients have reported severe side effects without appreciable symptomatic relief. Such patients must be considered unsuited for this therapy. Usually they have been or will prove to be similarly intolerant to other anticholinergic drugs. If methscopolamine bromide is to be used in a patient who gives a history of such intolerance, it should be started at a low dosage.

HOW SUPPLIED

Methscopolamine Bromide Tablets, USP 2.5 mg are available as white, round tablets, debossed with "BY1" on one side and plain on the other side, in the following package size:

Bottles of 100 (NDC 76385-100-01)

Methscopolamine Bromide Tablets, USP 5 mg are available as white, oval tablets, debossed with "BY2" on one side and plain on the other side, in the following package size:

Bottles of 60 (NDC 76385-101-60)

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

REFERENCES

1. Gilman A, Gilman AB, Goodman LA, eds.

The Pharmacological Basis of Therapeutics. 6th ed. New York: MacMillan Publishing Company.1980.

2. American Hospital Formulary Service. American Society of Hospital Pharmacists. Bethesda, Maryland.

3. Domino EF, Corasen G. Central and Peripheral Effects of Muscarinic Cholinergic Blocking Agents in

Man. *Anesthesiology* 1967;28:568-574.

4. Mogensen L, Orinius E. Arrhythmic Complications after Parasympathetic Treatment of Bradyarrhythmias in a Coronary Care Unit. *Acta Med Scand* 1971;190:495-498.

5. Neeld JB Jr., et al. Cardiac Rate and Rhythm Changes with Atropine and Methscopolamine. *Clin Pharmacol Ther* 1975;17(3):290-295.

Rx Only

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

Manufactured for:

Bayshore Pharmaceuticals LLC

Short Hills, NJ 07078

1-800-593-5725

Issued: 01/13

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 76385-100-01

Methscopolamine

Bromide Tablets,

USP

2.5 mg

Rx Only

100 Tablets

Bayshore

NDC 76385-101-60

Methscopolamine

Bromide Tablets,

USP

5 mg

Rx Only

60 Tablets

Bayshore

METHSCOPOLAMINE BROMIDE
methscopolamine bromide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76385-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHSCOPOLAMINE BROMIDE (UNII: RTN51LK7WL) (METHSCOPOLAMINE - UNII:VDR09VTQ8U)	METHSCOPOLAMINE BROMIDE	2.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	BY1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76385-100-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200602	10/01/2013	

METHSCOPOLAMINE BROMIDE

methscopolamine bromide tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76385-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

METHSCOPOLAMINE BROMIDE (UNII: RTN51LK7WL) (METHSCOPOLAMINE - UNII:VDR09VTQ8U)	METHSCOPOLAMINE BROMIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	BY2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76385-101-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200602	10/01/2013	

Labeler - BAYSHORE PHARMACEUTICALS LLC (968737416)

Registrant - BAYSHORE PHARMACEUTICALS LLC (968737416)

Revised: 1/2020 BAYSHORE PHARMACEUTICALS LLC