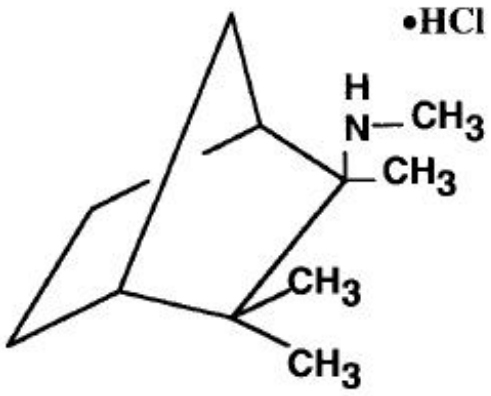
MECAMYLAMINE HYDROCHLORIDE- mecamylamine hydrochloride tablet
LGM Pharma Solutions, LLC

MECAMYLAMINE Hydrochloride Tablets, USP, 2.5 mg

DESCRIPTION

Mecamylamine HCl is a potent, oral antihypertension agent and ganglion blocker, and is a secondary amine. It is N,2,3,3-tetramethyl-bicyclo [2.2.1] heptan- 2 -amine hydrochloride. Its empirical formula is $C_{11}H_{21}N$ • HCl and its structural formula is:



It is a white, odorless, or practically odorless, crystalline powder, is highly stable, soluble in water and has a molecular weight of 203.75.

Mecamylamine HCl is supplied as tablets for oral use, each containing 2.5 mg mecamylamine HCl. Inactive ingredients are calcium phosphate, D&C Yellow 10, FD&C Yellow 6, lactose, magnesium stearate, cornstarch, and talc.

CLINICAL PHARMACOLOGY

Mecamylamine HCl reduces blood pressure in both normotensive and hypertensive individuals. It has a gradual onset of action (1/2 to 2 hours) and a long-lasting effect (usually 6 to 12 hours or more). A small oral dosage often produces a smooth and predictable reduction of blood pressure. Although this antihypertensive effect is predominantly orthostatic, the supine blood pressure is also significantly reduced.

Pharmacokinetics and Metabolism

Mecamylamine HCl is almost completely absorbed from the gastrointestinal tract, resulting in consistent lowering of blood pressure in most patients with hypertensive cardiovascular disease. Mecamylamine HCl is excreted slowly in the urine in the unchanged form. The rate of its renal elimination is influenced markedly by urinary pH. Alkalinization of the urine reduces, and acidification promotes, renal excretion of mecamylamine.

Mecamylamine HCl crosses the blood-brain and placental barriers.

INDICATIONS AND USAGE

For the management of moderately severe to severe essential hypertension and in uncomplicated cases of malignant hypertension.

CONTRAINDICATIONS

Mecamylamine HCl should not be used in mild, moderate, labile hypertension and may prove unsuitable in uncooperative patients. It is contraindicated in coronary insufficiency or recent myocardial infarction.

Mecamylamine HCl should be given with great discretion, if at all, when renal insufficiency is manifested by a rising or elevated BUN. The drug is contraindicated in uremia. Patients receiving antibiotics and sulfonamides should generally not be treated with ganglion blockers. Other contraindications are glaucoma, organic pyloric stenosis or hypersensitivity to the product.

WARNINGS

Mecamylamine, a secondary amine, readily penetrates the brain and thus may produce central nervous system effects. Tremor, choreiform movements, mental aberrations, and convulsions may occur rarely. These have occurred most often when large doses of Mecamylamine HCl were used, especially in patients with cerebral or renal insufficiency.

When ganglion blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. In patients with malignant hypertension and others, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure. When Mecamylamine HCl is withdrawn, this should be done gradually, and other antihypertensive therapy usually must be substituted. On the other hand, the effects of Mecamylamine HCl sometimes may last from hours to days after therapy is discontinued.

PRECAUTIONS

General

The patient's condition should be evaluated carefully, particularly as to renal and cardiovascular function. When renal, cerebral, or coronary blood flow is deficient, any additional impairment, which might result from added hypotension, must be avoided. The use of Mecamylamine HCl in patients with marked cerebral and coronary arteriosclerosis or after a recent cerebral accident requires caution.

The action of Mecamylamine HCl may be potentiated by excessive heat, fever, infection, hemorrhage, pregnancy, anesthesia, surgery, vigorous exercise, other antihypertensive drugs, alcohol, and salt depletion as a result of diminished intake or increased excretion due to diarrhea, vomiting, excessive sweating, or diuretics.

During therapy with Mecamylamine HCl, sodium intake should not be restricted but, if necessary, the dosage of the ganglion blocker must be adjusted.

Since urinary retention may occur in patients on ganglion blockers, caution is required in patients with prostatic hypertrophy, bladder neck obstruction, and urethral stricture.

Frequent loose bowel movements with abdominal distention and decreased borborygmi may be the first signs of paralytic ileus. If these are present, Mecamylamine HCl should be discontinued immediately and remedial steps taken.

Information for patients

Mecamylamine HCl may cause dizziness, lightheadedness, or fainting, especially when rising from a lying or sitting position. This effect may be increased by alcoholic beverages, exercise, or during hot weather. Getting up slowly may help alleviate such a reaction.

Drug Interactions

Patients receiving antibiotics and sulfonamides generally should not be treated with ganglion blockers.

The action of Mecamylamine HCl may be potentiated by anesthesia, other antihypertensive drugs and alcohol.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the effects upon fertility, mutagenic or carcinogenic potential of Mecamylamine HCl.

Pregnancy

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

Nursing Mothers

Because of the potential for serious adverse reactions in nursing infants from Mecamylamine HCl, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

The following adverse reactions have been reported and within each category are listed in order of decreasing severity.

Gastrointestinal: Ileus, constipation (sometimes preceded by small, frequent liquid stools), vomiting, nausea, anorexia, glossitis and dryness of mouth.

Cardiovascular: Orthostatic dizziness and syncope, postural hypotension.

Nervous System/Psychiatric: Convulsions, choreiform movements, mental aberrations, tremor, and paresthesias (see WARNINGS).

Respiratory: Interstitial pulmonary edema and fibrosis.

Urogenital: Urinary retention, impotence, decreased libido.

Special Senses: Blurred vision, dilated pupils.

Miscellaneous: Weakness, fatigue, sedation.

To report **SUSPECTED ADVERSE EVENTS**, contact LGM Pharma Solutions, LLC at 1-877-288-1495 or online at www.nexgenpharma.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

Signs of overdosage include: hypotension (which may progress to peripheral vascular collapse), postural hypotension, nausea, vomiting, diarrhea, constipation, paralytic ileus, urinary retention, dizziness, anxiety, dry mouth, mydriasis, blurred vision, or palpitations. A rise in intraocular pressure may occur.

Pressor amines may be used to counteract excessive hypotension. Since patients being treated with ganglion blockers are more than normally reactive to pressor amines, small doses of the latter are recommended to avoid excessive response.

The oral LD_{50} of Mecamylamine HCl in the mouse is 92 mg/kg.

DOSAGE AND ADMINISTRATION

Therapy is usually started with one 2.5 mg tablet of Mecamylamine HCl twice a day. This initial dosage should be modified by increments of one 2.5 mg tablet at intervals of not less than 2 days until the desired blood pressure response occurs (the criterion being a dosage just under that which causes signs of mild postural hypotension).

The average total daily dosage of Mecamylamine HCl is 25 mg, usually in three divided doses. However, as little as 2.5 mg daily may be sufficient to control hypertension in some patients. A range of two to four or even more doses may be required in severe cases when smooth control is difficult to obtain. In severe or urgent cases, larger increments at smaller intervals may be needed. Partial tolerance may develop in certain patients, requiring an increase in the daily dosage of Mecamylamine HCl.

Administration of Mecamylamine HCl after meals may cause a more gradual absorption and smoother control of excessively high blood pressure. The timing of doses in relation to meals should be consistent. Since the blood pressure response to antihypertensive drugs is increased in the early morning, the larger dose should be given at noontime and perhaps in the evening. The morning dose, as a rule, should be relatively small and in some instances may even be omitted.

The *initial regulation of dosage* should be determined by blood pressure readings in the erect position at the time of maximal effect of the drug, as well as by other signs and symptoms of orthostatic hypotension.

The *effective maintenance dosage* should be regulated by blood pressure readings in the erect position and by limitation of dosage to that which causes slight faintness or dizziness in this position. If the patient or a relative can use a sphygmomanometer, instructions may be given to reduce or omit a dose if readings fall below a designated level or if faintness or lightheadedness occurs. ***However, no change should be instituted without the knowledge of the physician.***

Close supervision and education of the patient, as well as critical adjustment of dosage, are essential to successful therapy.

Other Antihypertensive Agents

When Mecamylamine HCl is given with other antihypertensive drugs, the dosage of these other agents, as well as that of Mecamylamine HCl, should be reduced to avoid excessive hypotension. However, thiazides should be continued in their usual dosage, while that of Mecamylamine HCl is decreased by at least 50 percent.

HOW SUPPLIED

Mecamylamine HCl Tablets, 2.5 mg, are slightly yellow, round, compressed tablets, coded with “MP” on one side and “2.5” on the other side. They are supplied in bottles of 100 tablets, (NDC 79739-7183-1).

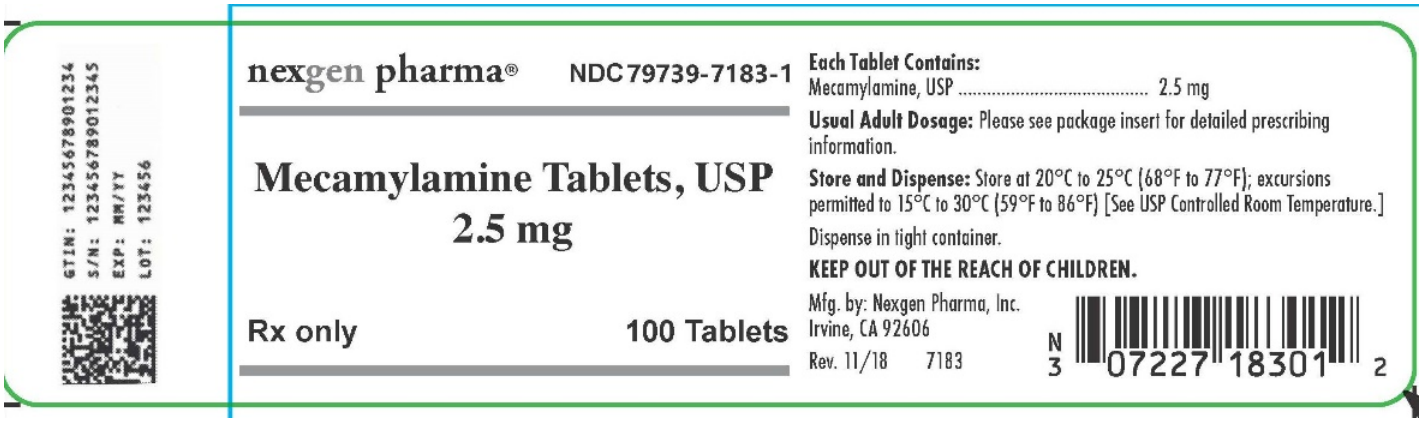
STORAGE CONDITION

Store at 20°C – 25°C (68°F – 77°F); excursions permitted to 15°C – 30°C (59°F – 86°F), [see USP Controlled Room Temperature]. Dispense in a tight container.

Manufactured by: Nexgen Pharma, Inc., Irvine, CA 92606, USA

Rev. 08/2020

PRINCIPAL DISPLAY PANEL



Mecamylamine 100 Count

MECAMYLAMINE HYDROCHLORIDE

mecamylamine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:79739-7183
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Mecamylamine Hydrochloride (UNII: 4956DJR58O) (Mecamylamine - UNII:6EE945D3OK)	Mecamylamine Hydrochloride	2.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
Talc (UNII: 7SEV7J4R1U)	
Water (UNII: 059QF0KO0R)	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	MP;2;5
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:79739-7183-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204054	03/19/2013	

Labeler - LGM Pharma Solutions, LLC (117549198)

Registrant - LGM Pharma Solutions, LLC (117549200)

Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549200	MANUFACTURE(79739-7183) , ANALYSIS(79739-7183) , PACK(79739-7183) , LABEL(79739-7183)

Revised: 8/2020 LGM Pharma Solutions, LLC