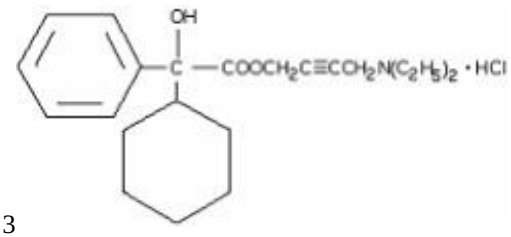
OXYBUTYNIN CHLORIDE - oxybutynin chloride tablet
State of Florida DOH Central Pharmacy

Oxybutynin Chloride Tablets, USP

DESCRIPTION

Oxybutynin chloride is a white crystalline solid, readily soluble in water and acids, but relatively insoluble in alkalis. Chemically, it is the d,i-(racemic) form of 4-diethyl-amino-2-butynyl phenylcyclohexylglycolate hydrochloride with the following formula:



$C_{22}H_{32}ClNO_3$ M.W. 393.9

Each tablet for oral administration contains oxybutynin chloride, USP 5 mg.

Inactive ingredients include calcium stearate, microcrystalline cellulose, anhydrous lactose, sodium starch glycolate and FD&C Blue #1.

CLINICAL PHARMACOLOGY

Oxybutynin chloride exerts direct antispasmodic effect on smooth muscle and inhibits the muscarinic action of acetylcholine on smooth muscle. It exhibits only one-fifth of the anticholinergic activity of atropine on the rabbit detrusor muscle, but four to ten times the antispasmodic activity. No blocking effects occur at skeletal neuromuscular junctions or autonomic ganglia (antinicotinic effects).

Oxybutynin relaxes bladder smooth muscle. In patients with conditions characterized by involuntary bladder contractions, cystometric studies have demonstrated that oxybutynin increases bladder (vesical) capacity, diminishes the frequency of uninhibited contractions of the detrusor muscle, and delays the initial desire to void. Oxybutynin thus decreases urgency and the frequency of both incontinent episodes and voluntary urination.

Oxybutynin chloride was well tolerated in patients administered the drug in controlled studies of 30 days duration and in uncontrolled studies in which some of the patients received the drug for two years. Pharmacokinetic information is not currently available.

INDICATIONS AND USAGE

Oxybutynin chloride tablets are indicated for the relief of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria).

CONTRAINDICATIONS

Oxybutynin chloride is contraindicated in patients with untreated angle closure glaucoma and in patients with untreated narrow anterior chamber angles since anticholinergic drugs may aggravate these conditions. It is also contraindicated in partial or complete obstruction of the gastrointestinal tract, paralytic ileus, intestinal atony of the elderly or debilitated patient, megacolon, toxic megacolon complicating ulcerative colitis, severe colitis and myasthenia gravis. It is contraindicated in patients with obstructive uropathy and in patients with unstable cardiovascular status in acute hemorrhage.

Oxybutynin chloride is contraindicated in patients who have demonstrated hypersensitivity to the product.

WARNINGS

Oxybutynin chloride, when administered in the presence of high environmental temperature, can cause heat prostration (fever and heat stroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with oxybutynin chloride would be inappropriate and possibly harmful.

Oxybutynin chloride 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.

Alcohol or other sedative drugs may enhance the drowsiness caused by oxybutynin.

PRECAUTIONS

Oxybutynin chloride should be used with caution in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease. Oxybutynin may aggravate the symptoms of hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, hiatal hernia, tachycardia, hypertension, and prostatic hypertrophy.

Administration of oxybutynin chloride to patients with ulcerative colitis may suppress intestinal motility to the point of producing a paralytic ileus and precipitate or aggravate toxic megacolon, a serious complication of the disease.

Carcinogenesis, Mutagenesis, Impairment of Fertility

A 24-month study in rats at dosages up to approximately 400 times the recommended human dosage showed no evidence of carcinogenicity.

Oxybutynin showed no increase in mutagenic activity when tested in *Schizosac-charomyces pompholiciformis*, *Saccharomyces cerevisiae*, and *Salmonella typhimurium* test symptoms. Reproduction studies in the hamster, rabbit, rat, and mouse have shown no definite evidence of impaired fertility.

Pregnancy

Category B: Reproduction studies in the hamster, rabbit, rat, and mouse have shown no definite evidence of impaired fertility or harm to the animal fetus. The safety of oxybutynin chloride administered to women who are or who may become pregnant has not been established. Therefore, oxybutynin should not be given to pregnant women unless, in the judgment of the physician, the probable clinical benefits outweigh the possible hazards.

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 oxybutynin chloride is administered to a nursing woman.

Pediatric Use

The safety and efficacy of oxybutynin chloride administration have been demonstrated for children 5 years of age and older (see **DOSAGE AND ADMINISTRATION**). However, as there is insufficient clinical data for children under age 5, oxybutynin is not recommended for this age group.

ADVERSE REACTIONS

Following administration of oxybutynin chloride, the symptoms that can be associated with the use of

other anticholinergic drugs may occur:

Cardiovascular: Palpitations, tachycardia, vasodilatation.

Dermatologic: Decreased sweating, rash.

Gastrointestinal/Genitourinary: Constipation, decreased gastrointestinal motility, dry mouth, nausea, urinary hesitance and retention.

Nervous System: Asthenia, dizziness, drowsiness, hallucinations, insomnia, restlessness.

Ophthalmic: Amblyopia, cycloplegia, decreased lacrimation, mydriasis.

Other: Impotence, suppression of lactation.

OVERDOSAGE

The symptoms of overdosage with oxybutynin chloride may be any of those seen with other anticholinergic agents. Symptoms may include signs of central nervous system excitation (e.g., restlessness, tremor, irritability, convulsions, delirium, hallucinations), flushing, fever, nausea, vomiting, tachycardia, hypotension or hypertension, respiratory failure, paralysis, or coma.

In the event of an overdose or exaggerated response, treatment should be symptomatic and supportive. Maintain respiration and induce emesis or perform gastric lavage (emesis is contraindicated in precomatose, convulsive, or psychotic state). Activated charcoal may be administered as well as a cathartic. Physostigmine may be considered to reverse symptoms of anticholinergic intoxication.

Hyperpyrexia may be treated symptomatically with ice bags or other cold applications and alcohol sponges.

DOSAGE AND ADMINISTRATION

Adults: The usual dose is one 5 mg tablet two to three times a day. The maximum recommended dose is one tablet (5 mg) four times a day.

Children over 5 years of age: The usual dose is one 5 mg tablet two times a day. The maximum recommended dose is one tablet (5 mg) three times a day.

HOW SUPPLIED

Oxybutynin Chloride Tablets, USP:

5 mg — Very pale blue, round, scored tablets.

Debossed: PLIVA 456

They are supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Strength	Quantity/Form	Color	Source Prod. Code
53808-0747-1	5 mg	30 Tablets in a Blister Pack	Very pale blue	50111-456

Dispense in a tight, light-resistant container as defined in the USP.

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

Manufactured by:

PLIVA®, Inc.

East Hanover, NJ 07936

This Product was Repackaged By:

State of Florida DOH Central Pharmacy
104-2 Hamilton Park Drive
Tallahassee, FL 32304
United States

Label Image 5mg

OXYBUTYNIN CHLORIDE

oxybutynin chloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53808-0747(NDC:50111-456)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBUTYNIN CHLORIDE (UNII: L9F3D9RENQ) (OXYBUTYNIN - UNII:K9P6MC7092)	OXYBUTYNIN CHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	blue (Very pale blue)	**Score**	2 pieces
Shape	ROUND (round)	**Size**	8mm
Flavor		**Imprint Code**	PLIVA;456
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53808-0747-1	30 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA071655	07/01/2009	

Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment

Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack

Revised: 6/2010 State of Florida DOH Central Pharmacy