CARBASTAT- carbachol injection, solution
Novartis Ophthalmics

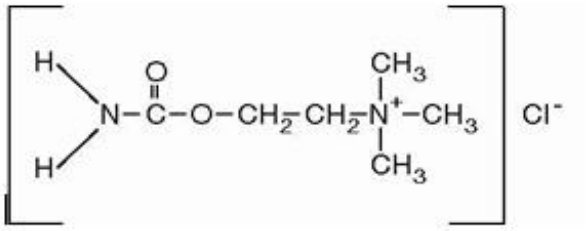
Carbastat®

Carbastat®

(CARBACHOL INTRAOCULAR SOLUTION, USP) 0.01%

DESCRIPTION

CARBASTAT® (Carbachol Intraocular Solution, USP) 0.01% is a sterile balanced salt solution of carbachol for intraocular injection. The active ingredient is represented by the structural formula:



MW = 182.65

Established name: Carbachol

Chemical name: Ethanaminium, 2-[(aminocarbonyl)oxy]-*N*,*N*,*N* -trimethyl-, chloride.

Each mL contains: Active: Carbachol 0.01%.

Inactive: Sodium chloride 0.64%, potassium chloride 0.075%, calcium chloride dihydrate 0.048%, magnesium chloride hexahydrate 0.03%, sodium acetate trihydrate 0.39%, sodium citrate dihydrate 0.17%, sodium hydroxide and/or hydrochloric acid to adjust pH (5.0-7.5) and water for injection USP.

CLINICAL PHARMACOLOGY

Carbachol is a potent cholinergic (parasympathomimetic) agent which produces constriction of the iris and ciliary body resulting in reduction in intraocular pressure. The exact mechanism by which carbachol lowers intraocular pressure is not precisely known.

INDICATIONS AND USAGE

Intraocular use for obtaining miosis during surgery. In addition, Carbastat® (Carbachol Intraocular Solution USP) reduces the intensity of intraocular pressure elevation in the first 24 hours after cataract surgery.

CONTRAINDICATIONS

Should not be used in those persons showing hypersensitivity to any of the components of this preparation.

WARNINGS

For single-dose intraocular use only. Discard unused portion. Intraocular carbachol 0.01% should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, G.I. spasm, urinary tract obstruction and Parkinson's disease.

PRECAUTIONS

Carcinogenesis

Studies in animals to evaluate the carcinogenic potential have not been conducted.

Pregnancy: Category C.

There are no adequate and well controlled studies in pregnant women. Carbastat® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known if this medication is excreted in breast milk. Exercise caution when administering to a nursing woman.

Pediatric Use

Safety and efficacy in pediatric patients have not been established.

ADVERSE REACTIONS

Ocular

Corneal clouding, persistent bullous keratopathy, retinal detachment and postoperative iritis following cataract extraction have been reported.

Systemic

Side effects such as flushing, sweating, epigastric distress, abdominal cramps, tightness in urinary bladder, and headache have been reported with topical or systemic application of carbachol.

DOSAGE AND ADMINISTRATION

Aseptically remove the sterile vial from the blister package by peeling the backing paper and dropping the vial onto a sterile tray. Withdraw the contents into a dry sterile syringe, and replace the needle with an atraumatic cannula prior to intraocular irrigation. No more than one-half milliliter should be gently instilled into the anterior chamber for the production of satisfactory miosis. It may be instilled before or after securing sutures. Miosis is usually maximal within two to five minutes after application.

HOW SUPPLIED

CARBASTAT (Carbachol Intraocular Solution, USP) 0.01%

1.5 mL sterile glass vials in cartons of 12 (12 x 1.5 mL)

NDC 58768-735-12

Store at controlled room temperature 15°-30°C (59°-86°F).

Rx only

Manufactured by OMJ Pharmaceuticals, Inc.,

San Germán, P.R. 00683

for Novartis Ophthalmics

Duluth, GA 30097

5007-D

March, 2001

CARBASTAT

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58768-735
Route of Administration	INTRAOCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Carbachol (UNII: 8Y164V895Y) (Carbachol - UNII:8Y164V895Y)		0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
calcium chloride dihydrate (UNII: M4I0D6VV5M)	0.481 mg in 1 mL
hydrochloric acid (UNII: QTT17582CB)	
magnesium chloride hexahydrate (UNII: 02F3473H9O)	0.3 mg in 1 mL
potassium chloride (UNII: 660YQ98I10)	0.75 mg in 1 mL
sodium acetate trihydrate (UNII: 4550K0SC9B)	3.9 mg in 1 mL
Sodium chloride (UNII: 451W47IQ8X)	6.4 mg in 1 mL
sodium citrate dihydrate (UNII: B22547B95K)	1.7 mg in 1 mL
sodium hydroxide (UNII: 55X04QC32I)	
water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58768-735-12	12 in 1 CARTON		
1		1.5 mL in 1 VIAL, GLASS		

Labeler - Novartis Ophthalmics

Revised: 9/2006 Novartis Ophthalmics