

**OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION - olopatadine
hydrochloride ophthalmic solution
Gland Pharma Limited**

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

BULK LABEL

NDC 68083-398-85

Olopatadine Hydrochloride Ophthalmic Solution, USP, 0.7%.

Quantity- 1,000 - 2.5 mL fill Bottles

Batch No. : AXXXXXXX

Exp. Date : MM/YYYY

Store at 2°-25°C (36°-77°F)

CAUTION: For Manufacturing, processing or repackaging only.

Manufactured by :

Gland Pharma Limited

D.P. Pally, Hyderabad - 500043, INDIA

Code: AP/DRUGS/103/97

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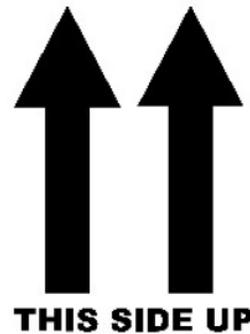
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OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION

olopatadine hydrochloride ophthalmic solution

Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:68083-398
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE	7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

BORIC ACID (UNII: R57ZHV85D4)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
HYDROXYPROPYL .GAMMA.-CYCLODEXTRIN (UNII: P6BYU725IU)	
HYPROMELLOSE 2910 (4000 MPA.S) (UNII: RN3152OP35)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68083-398-85	1000 in 1 CASE	01/06/2026	
1		2.5 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXPORT ONLY		01/06/2026	

Labeler - Gland Pharma Limited (918601238)

Establishment			
Name	Address	ID/FEI	Business Operations
GLAND PHARMA LIMITED		918601238	ANALYSIS(68083-398) , MANUFACTURE(68083-398) , PACK(68083-398)

Revised: 1/2026

Gland Pharma Limited