

DORZOLAMIDE AND TIMOLOL- dorzolamide hydrochloride and timolol maleate solution
FDC Limited

Dorzolamide hydrochloride and timolol maleate ophthalmic solution

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

DORZOLAMIDE AND TIMOLOL

dorzolamide hydrochloride and timolol maleate solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:55545-1007
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DORZOLAMIDE HYDROCHLORIDE (UNII: QZO5366EW7) (DORZOLAMIDE - UNII:9JDX055TW1)	DORZOLAMIDE	20 mg in 1 mL
TIMOLOL MALEATE (UNII: P8 Y54F70 1R) (TIMOLOL ANHYDROUS - UNII:5JKY92S7BR)	TIMOLOL ANHYDROUS	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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MANNITOL (UNII: 3OWL53L36A)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
HYDROXYETHYL CELLULOSE (2000 MPAS AT 1%) (UNII: S38J6RZN16)	
HYDROXYETHYL CELLULOSE (4000 MPAS AT 1%) (UNII: ZYD53NBL45)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55545-1007-1	1 in 1 CARTON	11/16/2019	
1		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:55545-1007-2	1 in 1 CARTON	11/16/2019	
2		10 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205295	11/16/2019	

Labeler - FDC Limited (650441301)

Registrant - FDC Limited (650078413)

Establishment

Name	Address	ID/FEI	Business Operations
FDC Limited		862267994	analysis(55545-1007) , manufacture(55545-1007)