DORZOLAMIDE HYDROCHLORIDE- dorzolamide hydrochloride solution
FDC Limited

Dorzolamide hydrochloride Ophthalmic Solution

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

DORZOLAMIDE HYDROCHLORIDE

dorzolamide hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55545-1008
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

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROXYETHYL CELLULOSE (2000 MPA.S AT 1%) (UNII: S38J6RZN16)	

HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55545-1008-1	1 in 1 CARTON	11/16/2019	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55545-1008-2	1 in 1 CARTON	11/16/2019	
2		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205294	11/16/2019	

Labeler - FDC Limited (650441301)

Registrant - FDC Limited (650078413)

Establishment

Name	Address	ID/FEI	Business Operations
FDC Limited		862267994	analysis(55545-1008) , manufacture(55545-1008)

Revised: 11/2019 FDC Limited