

dextran 70, polyethylene glycol 400, povidone, tetrahydrozoline hydrochloride solution/ drops

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55651-003	
Route of Administration	OPHTHALMIC			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
DEXTRAN 70 (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)		DEXTRAN 70	0.1 g in 100 mL	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)		POLYETHYLENE GLYCOL 400	1 g in 100 mL	
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)		POVIDONE	1 g in 100 mL	
TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)		TETRAHYDROZOLINE HYDROCHLORIDE	0.05 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
BORIC ACID (UNII: R57ZHV85D4)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
WATER (UNII: 059QF0KO0R)				
SODIUM BORATE (UNII: 91MBZ8H3QO)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55651-003-01	1 in 1 BOX	03/19/2023	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only			03/19/2023	

Labeler - K.C. Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc		174450460	manufacture(55651-003) , label(55651-003) , pack(55651-003)

