

COLESEVELAM- colesevelam tablet
Cadila Healthcare Limited

COLESEVELAM HYDROCHLORIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Colesevelam Hydrochloride Tablets, 625 mg

NDC 70771-1368-8

180 Tablets

Rx only



Over Coding Template

No Varnished Area (Do Not Print)
 (22 x 60 mm)

NDC 70771-1368-8

Colesevelam Hydrochloride Tablets

625 mg

180 Tablets
Rx only

zydus pharmaceuticals

Each film-coated tablet contains:
 Colesevelam hydrochloride 625 mg.

Dosage and use: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F)
 [see USP Controlled Room Temperature].
 Protect from moisture.

Dispense in a tight container as defined in the USP with a child-resistant closure.

Keep this and all drugs out of the reach of children.

Manufactured by:
 Cadila Healthcare Ltd.
 Ahmedabad, India

Rev.: 10/19

COLESEVELAM

colesevelam tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1368
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COLESEVELAM HYDROCHLORIDE (UNII: P4SG24W5Q) (COLESEVELAM - UNII:1XU104G55N)	COLESEVELAM HYDROCHLORIDE	625 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	CAPSULE (Modified Capsule)	Size	20 mm
Flavor		Imprint Code	619
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1368-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2019	
2	NDC:70771-1368-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2019	
3	NDC:70771-1368-4	10 in 1 CARTON	10/11/2019	
3	NDC:70771-1368-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207765	10/11/2019	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1368) , MANUFACTURE(70771-1368)

Revised: 8/2020

Cadila Healthcare Limited