

SEVELAMER CARBONATE - sevelamer carbonate tablet, film coated
Zydus Lifesciences Limited

Sevelamer Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1520-8

Sevelamer Tablets, 800 mg

270 Tablets

Rx only



SEVELAMER CARBONATE

sevelamer carbonate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1520
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SEVELAMER CARBONATE (UNII: 9YCX42I8IU) (SEVELAMER - UNII:941N5DUU5C)	SEVELAMER CARBONATE	800 mg

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
CROSPROVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
DIBUTYL SEBACATE (UNII: 4W5IH7FLNY)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
HYPROMELLOSE 2910 (50 MPA.S) (UNII: 1IVH67816N)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	WHITE (off-white to pale yellow)	Score	no score
Shape	CAPSULE (MODIFIED CAPSULE)	Size	20mm
Flavor		Imprint Code	824
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1520-8	270 in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2020	
2	NDC:70771-1520-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2020	
3	NDC:70771-1520-4	10 in 1 CARTON	09/17/2020	
3	NDC:70771-1520-2	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	ANDA207759	09/17/2020	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1520) , MANUFACTURE(70771-1520)

Revised: 10/2022

Zydus Lifesciences Limited