

COLESEVELAM- colesevelam tablet
Zydus Lifesciences Limited

COLESEVELAM HYDROCHLORIDE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Colesevelam Hydrochloride Tablets, 625 mg

NDC 70771-1368-8

180 Tablets

Rx only



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) | |
| CROSPROVIDONE (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: 70097M6130) | |
| METHACRYLIC ACID (UNII: 1CS02G8656) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE (UNII: FZ989GH94E) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SHELLAC (UNII: 46N107B710) | |
| 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 | 20mm |
| 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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|--|
| Zydus Lifesciences Limited | | 863362789 | ANALYSIS(70771-1368) , MANUFACTURE(70771-1368) |

Revised: 11/2024

Zydus Lifesciences Limited