

**MESALAMINE - mesalamine capsule, extended release**  
**Cadila Healthcare Limited**

**MESALAMINE Extended-Release Capsules**

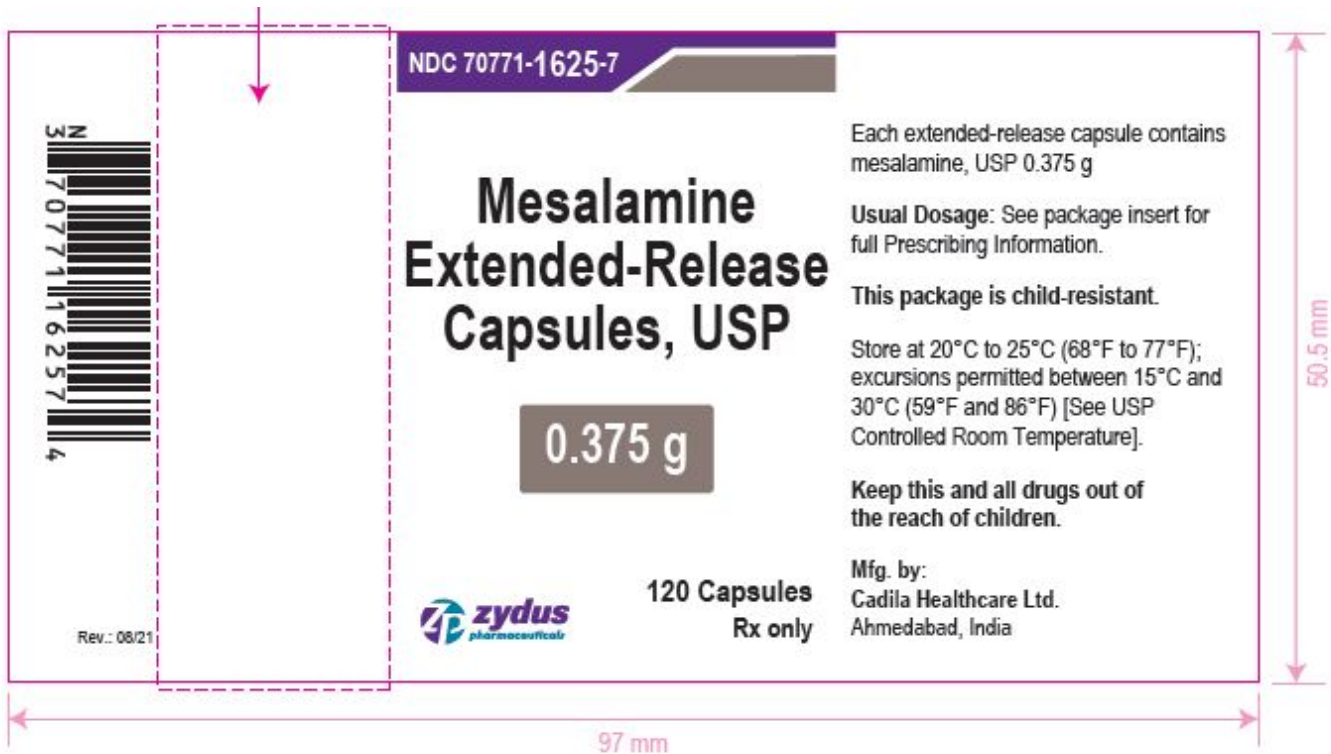
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Mesalamine Extended-Release Capsules, 0.375 g

120 capsules

NDC 70771-1625-7

Rx only



**MESALAMINE**

mesalamine capsule, extended release

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1625
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
MESALAMINE (UNII: 4Q81I59GXC) (MESALAMINE - UNII:4Q81I59GXC)	MESALAMINE	0.375 g

### Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SUCROSE (UNII: C151H8M554)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

Color	BLUE (opaque blue cap) , BLUE (opaque blue body)	Score	no score
Shape	CAPSULE	Size	24mm
Flavor		Imprint Code	452
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1625-7	120 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208954	08/13/2021	

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (863362789)

## Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1625) , MANUFACTURE(70771-1625)

Revised: 8/2021

Cadila Healthcare Limited