

MESALAMINE - mesalamine capsule, extended release
Zydus Lifesciences Limited

MESALAMINE Extended-Release Capsules

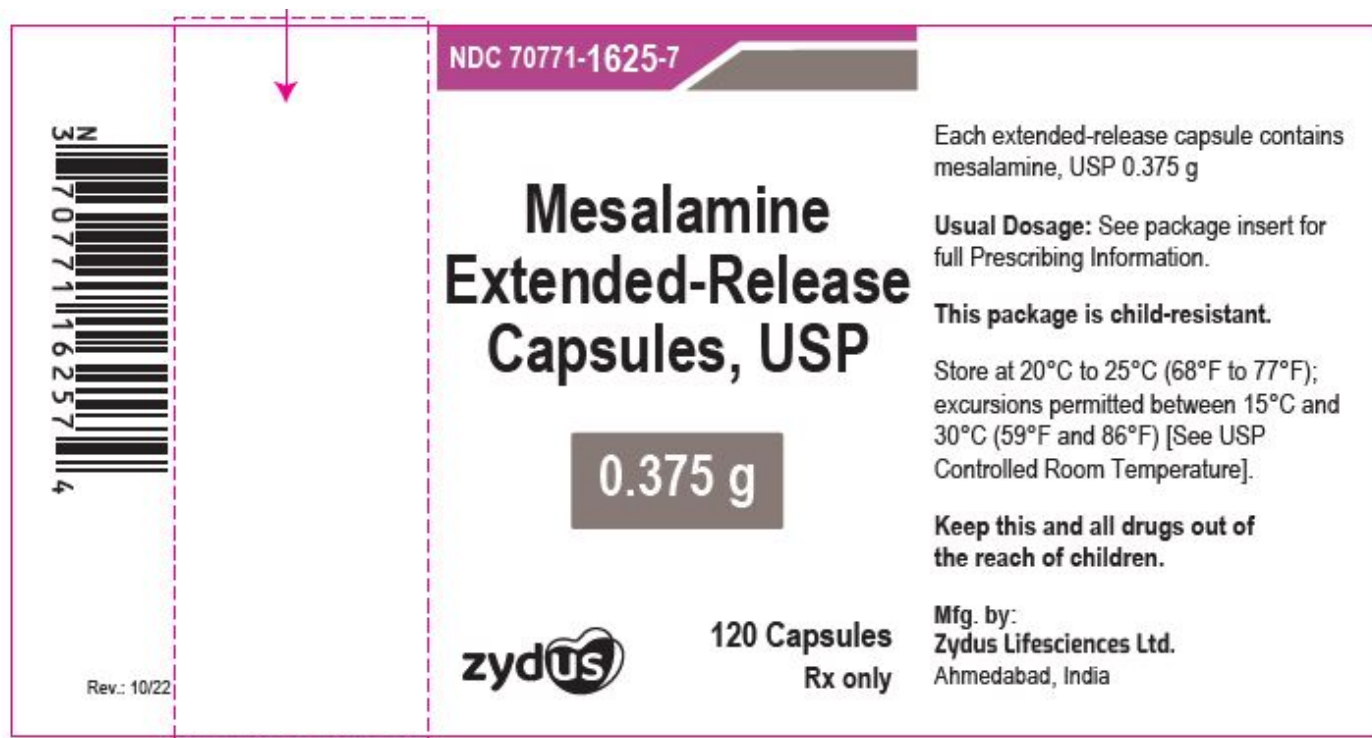
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Mesalamine Extended-Release Capsules, 0.375 g

120 capsules

NDC 70771-1625-7

Rx only



MESALAMINE

mesalamine capsule, extended release

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)		
FERROSO FERRIC 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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

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

Revised: 10/2022

Zydus Lifesciences Limited