

ZALDYON - mesalamine tablet, delayed release
Zydus Lifesciences Limited

ZALDYON (mesalamine) DELAYED-RELEASE TABLETS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

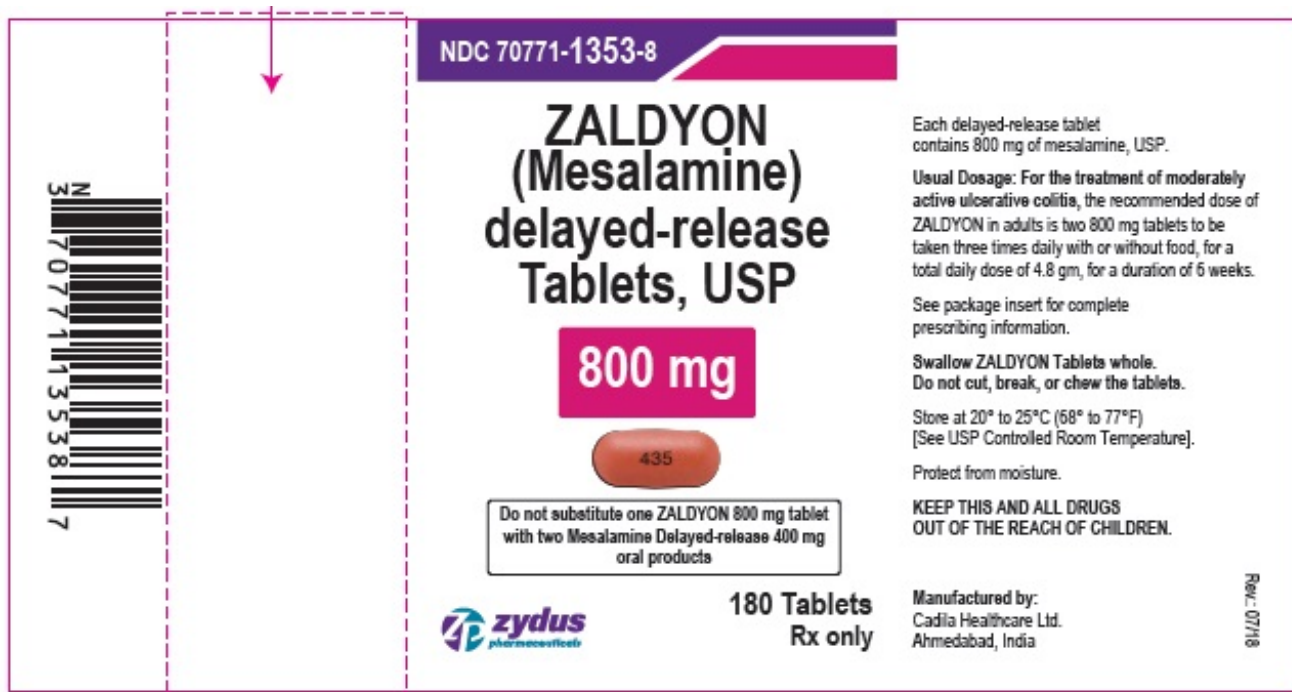
NDC 70771-1353-8 in bottle of 180 tablets

ZALDYON (Mesalamine) delayed-release Tablets USP, 800 mg

R_x only

180 tablets

ZYDUS



ZALDYON

mesalamine tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1353
---------------------	-------------------------	---------------------------	----------------

Route of Administration	ORAL
--------------------------------	------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MESALAMINE (UNII: 4Q81I59GXC) (MESALAMINE - UNII:4Q81I59GXC)	MESALAMINE	800 mg

Inactive Ingredients

Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIA (UNII: 5138Q19F1X)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	RED (REDDISH-BROWN)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	435
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1353-4	10 in 1 CARTON	01/17/2019	
1	NDC:70771-1353-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1353-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

ANDA	ANDA203286	01/17/2019	
------	------------	------------	--

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1353) , MANUFACTURE(70771-1353)

Revised: 10/2022

Zydus Lifesciences Limited