ALBENDAZOLE - albendazole tablet, film coated
Zydus Lifesciences Limited

ALBENDAZOLE tablets, for oral use

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1103-7

Albendazole Tablets USP, 200 mg

28 Tablets

Rx only

ALBENDAZOLE
albendazole tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1103
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALBENDAZOLE (UNII: F4216019LN) (ALBENDAZOLE - UNII:F4216019LN)	ALBENDAZOLE	200 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	12mm
Flavor		**Imprint Code**	1021
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1103-7	28 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	
2	NDC:70771-1103-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	
3	NDC:70771-1103-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/17/2018	
4	NDC:70771-1103-8	1 in 1 BOTTLE	12/17/2018	
4		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:70771-1103-6	2 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2020	
6	NDC:70771-1103-3	1 in 1 CARTON	05/27/2020	
6		2 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	ANDA208979	12/17/2018	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1103) , MANUFACTURE(70771-1103)

Revised: 10/2022

Zydus Lifesciences Limited