BUDESONIDE - budesonide capsule, coated pellets
Zydus Lifesciences Limited

BUDESONIDE DELAYED-RELEASE CAPSULES (ENTERIC COATED)

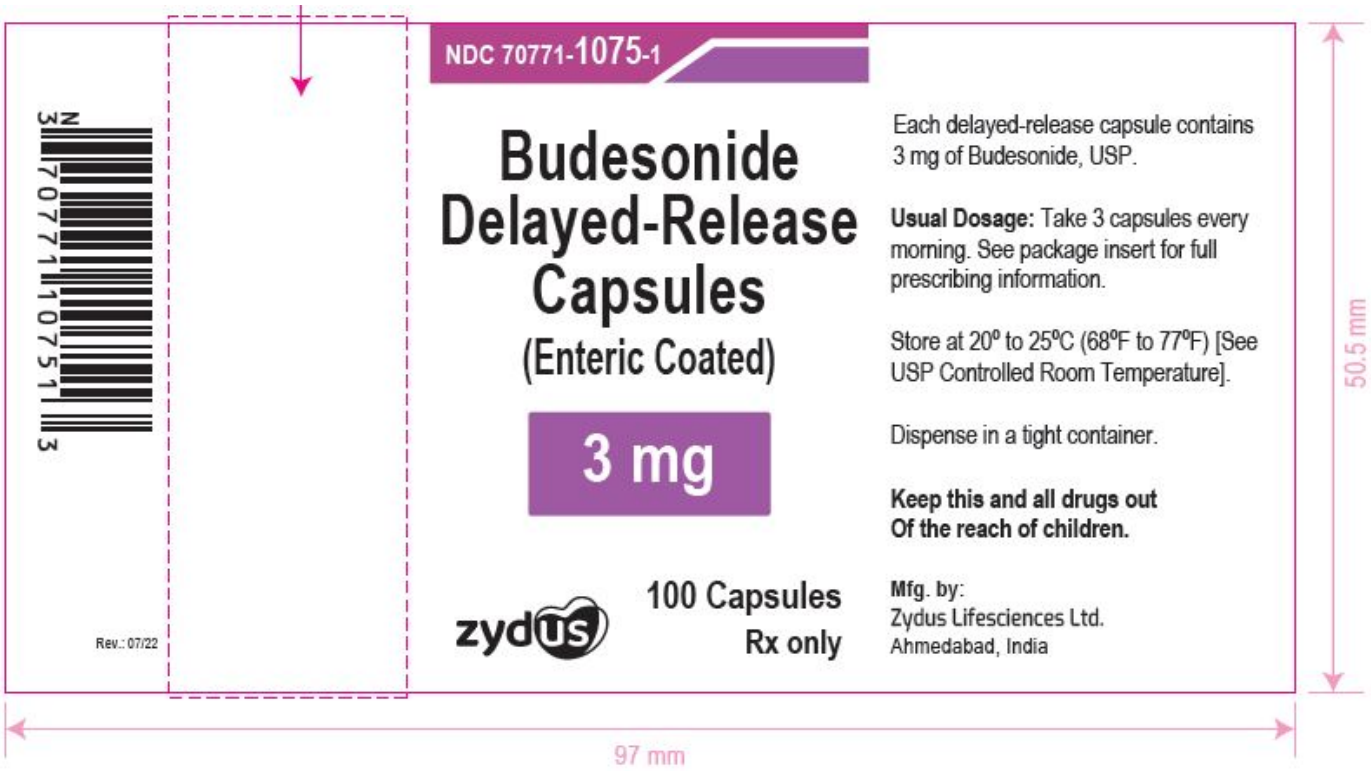
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1075-1 in bottle of 100 capsules

Budesonide Delayed-Release Capsules (Enteric Coated) 3 mg

100 capsules

Rx only



BUDESONIDE

budesonide capsule, coated pellets

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1075
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

BUDESONIDE (UNII: Q3OKS62Q6X) (BUDESONIDE - UNII:Q3OKS62Q6X)	BUDESONIDE	3 mg

Inactive Ingredients

Ingredient Name	Strength
ACETYLTRIBUTYL CITRATE (UNII: 0ZBX0N59RZ)	
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE (OPAQUE LIGHT-ORANGE) , WHITE (OPAQUE WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	720
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1075-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2017	
2	NDC:70771-1075-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2017	
3	NDC:70771-1075-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2017	
4	NDC:70771-1075-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2017	
5	NDC:70771-1075-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	06/08/2017	
6	NDC:70771-1075-4	10 in 1 CARTON	06/08/2017	

6		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	ANDA206134	06/08/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1075) , MANUFACTURE(70771-1075)

Revised: 7/2022 Zydus Lifesciences Limited