EZETIMIBE - ezetimibe tablet
Zydus Lifesciences Limited

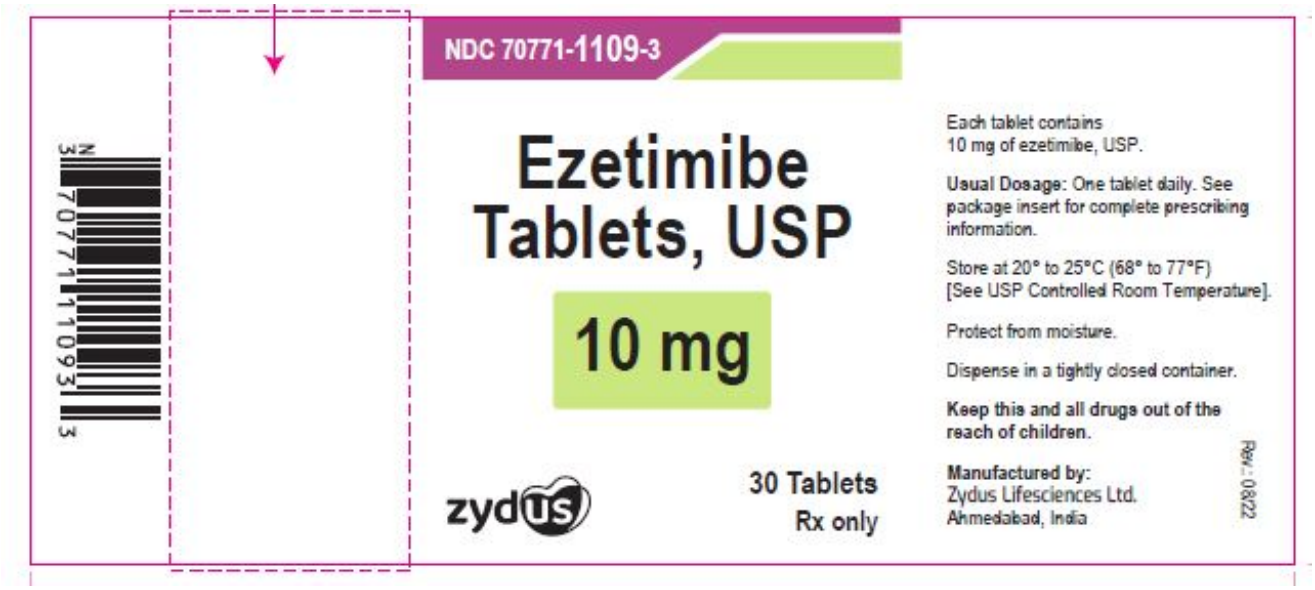
EZETIMIBE TABLETS

NDC 70771-1109-3 in bottle of 30 tablets

Ezetimibe Tablets , 10 mg

Rx only

30 tablets



EZETIMIBE

ezetimibe tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1109
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
EZETIMIBE (UNII: EOR26LQQ24) (EZETIMIBE - UNII:EOR26LQQ24)	EZETIMIBE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	9mm
Flavor		**Imprint Code**	773
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1109-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2017	
2	NDC:70771-1109-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2017	
3	NDC:70771-1109-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2017	
4	NDC:70771-1109-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2017	
5	NDC:70771-1109-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/09/2017	
6	NDC:70771-1109-4	10 in 1 CARTON	08/09/2017	
6	NDC:70771-1109-2	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	ANDA204331	08/09/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1109) , MANUFACTURE(70771-1109)