

FINGOLIMOD- fingolimod capsule
Zydus Lifesciences Limited

Fingolimod Capsules

SPL MEDGUIDE

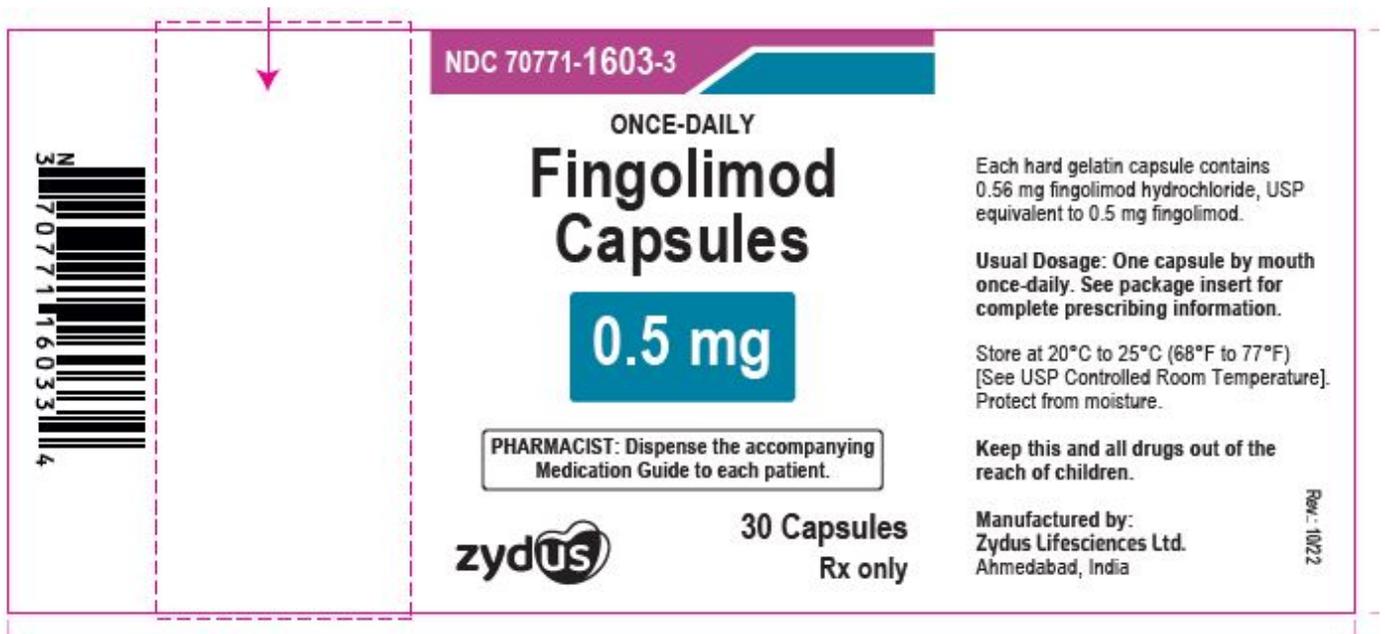
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1603-3

Fingolimod Capsules, 0.5 mg

30 Capsules

Rx only



FINGOLIMOD

fingolimod capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1603
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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FINGOLIMOD HYDROCHLORIDE (UNII: G926EC510T) (FINGOLIMOD - UNII:3QN8BYN5QF)	FINGOLIMOD	0.5 mg
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Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	WHITE (WHITE OPAQUE BODY) , YELLOW (YELLOW OPAQUE CAP)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	16mm
Flavor		Imprint Code	912
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1603-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2022	
2	NDC:70771-1603-7	1 in 1 CARTON	10/11/2022	
2		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:70771-1603-8	4 in 1 CARTON	10/11/2022	
3		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:70771-1603-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2022	
5	NDC:70771-1603-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/11/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
ANDA	ANDA207994	10/11/2022	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1603) , MANUFACTURE(70771-1603)

Revised: 11/2024

Zydus Lifesciences Limited