

**FINGOLIMOD- fingolimod capsule**  
**Zydus Lifesciences Limited**

**Fingolimod Capsules**

**SPL MEDGUIDE**

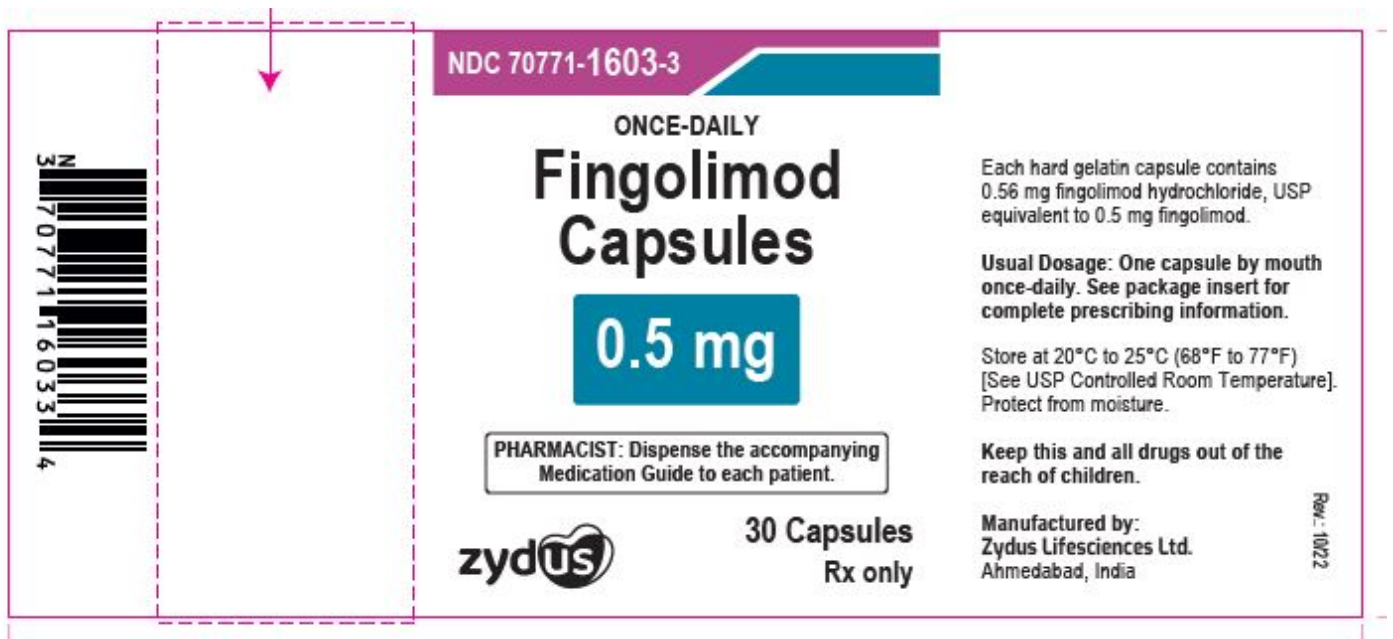
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1603-3

Fingolimod Capsules, 0.5 mg

30 Capsules

Rx only



**FINGOLIMOD**

fingolimod capsule

**Product Information**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
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<b>FINGOLIMOD HYDROCHLORIDE</b> (UNII: G926EC510T) (FINGOLIMOD - UNII:3QN8BYN5QF)	FINGOLIMOD	0.5 mg
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### Inactive Ingredients

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

### Product Characteristics

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

### 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: 9/2023

Zydus Lifesciences Limited