

**TOFACITINIB- tofacitinib tablet, film coated**  
**Zydus Lifesciences Limited**

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**TOFACITINIB tablets, for oral use**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Tofacitinib Tablets, 5 mg

NDC 70771-1821-6

60 Tablets

Rx only



**TOFACITINIB**

tofacitinib tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1821
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TOFACITINIB CITRATE</b> (UNII: O1FF4DIV0D) (TOFACITINIB - UNII:87LA6FU830)	TOFACITINIB	5 mg

## Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

## Product Characteristics

Color	WHITE (OFF WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	8mm
Flavor		Imprint Code	1243
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1821-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2026	
2	NDC:70771-1821-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/11/2026	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209829	05/11/2026	

**Labeler** - Zydus Lifesciences Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1821) , MANUFACTURE(70771-1821)

Revised: 5/2026

Zydus Lifesciences Limited