ROFLUMILAST- roflumilast tablet
Zydus Lifesciences Limited

Roflumilast Tablets, for oral use

SPL MEDGUIDE

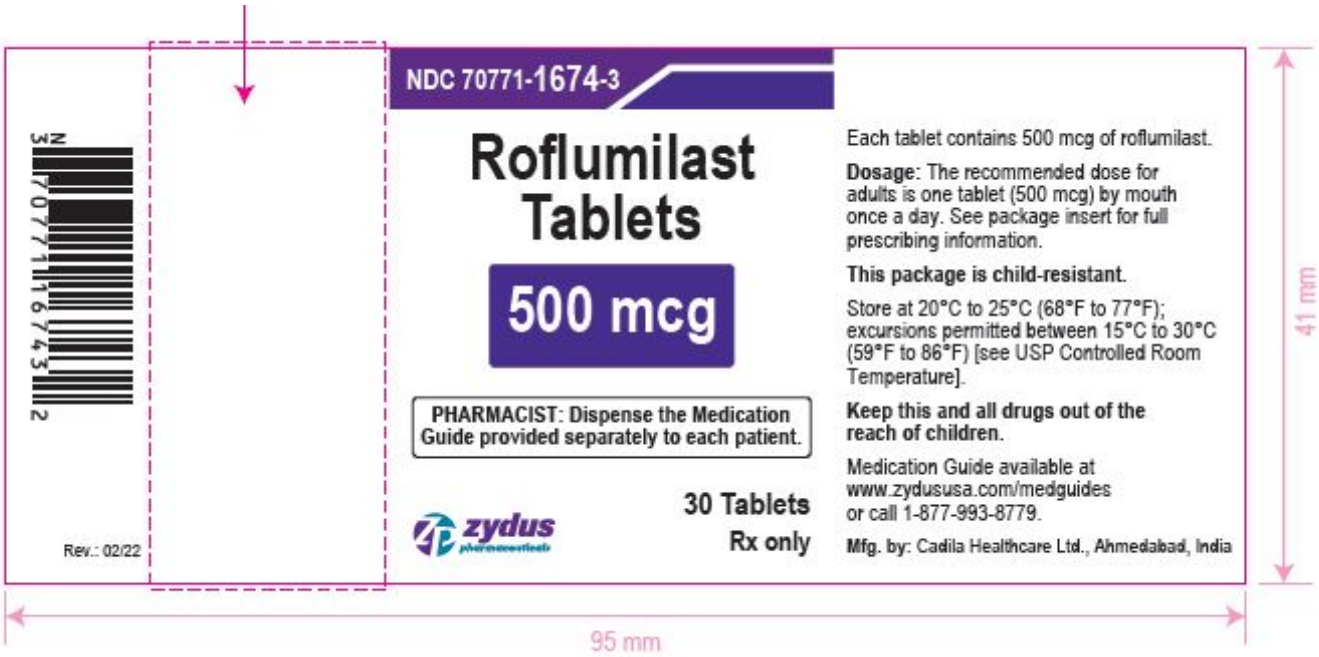
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1674-3

Roflumilast Tablets, 500 mcg

30 tablets

Rx only

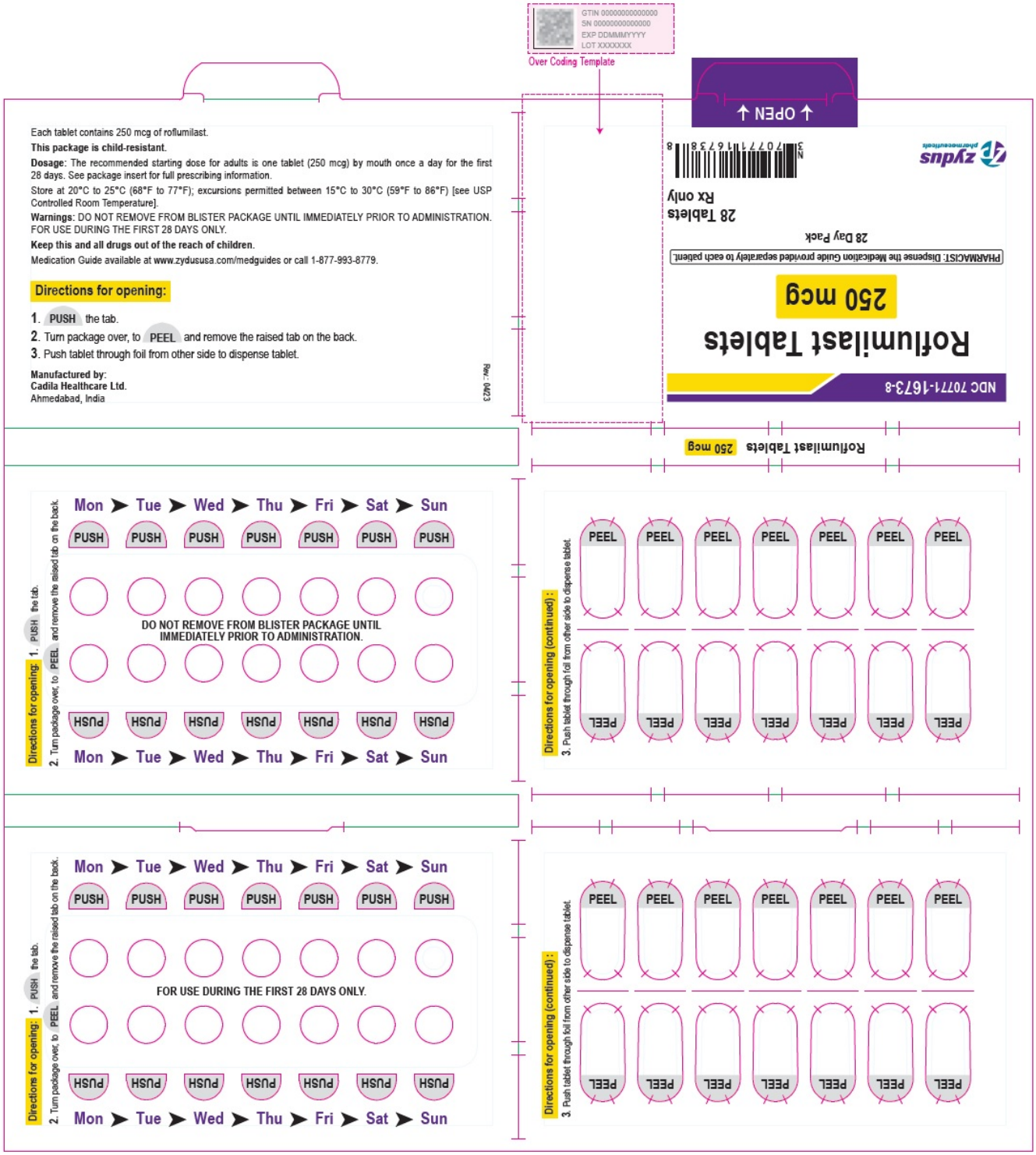


NDC 70771-1673-8

Roflumilast Tablets, 250 mcg

Blister pack of 28 tablets

Rx only



ROFLUMILAST

roflumilast tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1674
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ROFLUMILAST (UNII: 0P6C6ZOP5U) (ROFLUMILAST - UNII:0P6C6ZOP5U)	ROFLUMILAST	500 ug

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	T5
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1674-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2022	
2	NDC:70771-1674-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208303	10/03/2022	

ROFLUMILAST

roflumilast tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1673
Route of Administration	ORAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
ROFLUMILAST (UNII: 0P6C6ZOP5U) (ROFLUMILAST - UNII:0P6C6ZOP5U)	ROFLUMILAST	250 ug

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	T6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1673-8	1 in 1 CARTON	05/18/2023	
1		28 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70771-1673-3	2 in 1 CARTON	05/18/2023	
2	NDC:70771-1673-2	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	ANDA208303	05/18/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1673, 70771-1674) , MANUFACTURE(70771-1673, 70771-1674)