LUBIPROSTONE - lubiprostone capsule
Zydus Lifesciences Limited

Lubiprostone Capsules

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1763-6

Lubiprostone Capsules, 8 mcg

60 Capsules

Rx only

NDC 70771-1764-6

Lubiprostone Capsules, 24 mcg

60 Capsules

Rx only

LUBIPROSTONE

lubiprostone capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1763
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LUBIPROSTONE (UNII: 7662KG2R6K) (LUBIPROSTONE - UNII:7662KG2R6K)	LUBIPROSTONE	8 ug

Inactive Ingredients	
Ingredient Name	**Strength**
1,4-SORBITAN (UNII: AV0YTZ4E6J)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	PINK (light pink to pink colored)	**Score**	no score

Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1763-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	
2	NDC:70771-1763-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214131	03/23/2023	

LUBIPROSTONE

lubiprostone capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1764
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LUBIPROSTONE (UNII: 7662KG2R6K) (LUBIPROSTONE - UNII:7662KG2R6K)	LUBIPROSTONE	24 ug

Inactive Ingredients

Ingredient Name	Strength
1,4-SORBITAN (UNII: AV0YTZ4E6J)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (light yellow colored)	**Score**	no score
Shape	OVAL	**Size**	9mm

Flavor		**Imprint Code**	24
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1764-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	
2	NDC:70771-1764-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/23/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214131	03/23/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1763, 70771-1764) , MANUFACTURE(70771-1763, 70771-1764)

Revised: 3/2023 Zydus Lifesciences Limited