

SOLIFENACIN - solifenacin tablet, film coated
Zydus Lifesciences Limited

Solifenacin Succinate Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1604-3

Solifenacin succinate tablets, 5 mg

Rx only

30 tablets



NDC 70771-1605-3

Solifenacin succinate tablets, 10 mg

Rx only

30 tablets



SOLIFENACIN

solifenacin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1604
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SOLIFENACIN SUCCINATE (UNII: KKA5DLD701) (SOLIFENACIN - UNII:A8910SQ1U)	SOLIFENACIN SUCCINATE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	YELLOW (LIGHT YELLOW)	Score	no score
Shape	ROUND (BICONVEX)	Size	8mm

Flavor		Imprint Code	987	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1604-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2022	
2	NDC:70771-1604-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA207721	02/10/2022		

SOLIFENACIN			
solifenacin tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1605
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SOLIFENACIN SUCCINATE (UNII: KKA5DLD701) (SOLIFENACIN - UNII:A8910SQJ1U)	SOLIFENACIN SUCCINATE	10 mg	
Inactive Ingredients			
Ingredient Name	Strength		
STARCH, CORN (UNII: O8232NY3SJ)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
TALC (UNII: 7SEV7J4R1U)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
Product Characteristics			
Color	WHITE (LIGHT PINK)	Score	no score
Shape	ROUND (BICONVEX)	Size	8mm

Flavor		Imprint Code	988	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1605-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2022	
2	NDC:70771-1605-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA207721	02/10/2022		

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1604, 70771-1605) , MANUFACTURE(70771-1604, 70771-1605)

Revised: 10/2022

Zydus Lifesciences Limited