DARUNAVIR- darunavir tablet, film coated
Zydus Lifesciences Limited

Darunavir Tablets

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1745-6

Darunavir tablets, 600 mg

60 Tablets

Rx only

NDC 70771-1746-3

Darunavir tablets, 800 mg

30 Tablets

Rx only

DARUNAVIR

darunavir tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1745
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DARUNAVIR (UNII: YO603Y8113) (DARUNAVIR - UNII:YO603Y8113)	DARUNAVIR	600 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BROWN	**Score**	no score

Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	1215
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1745-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	
2	NDC:70771-1745-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	
3	NDC:70771-1745-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214085	05/01/2024	

DARUNAVIR

darunavir tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1746
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DARUNAVIR (UNII: YO603Y8113) (DARUNAVIR - UNII:YO603Y8113)	DARUNAVIR	800 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	YELLOW (beige colored)	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	1217
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1746-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	
2	NDC:70771-1746-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	
3	NDC:70771-1746-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214085	05/01/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1745, 70771-1746) , MANUFACTURE(70771-1745, 70771-1746)

Revised: 4/2024 Zydus Lifesciences Limited