EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE- emtricitabine and tenofovir disoproxil fumarate tablet, film coated
Zydus Lifesciences Limited

Emtricitabine and Tenofovir Disoproxil Fumarate Tablets

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1620-3

Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 100 mg/150 mg

Rx Only

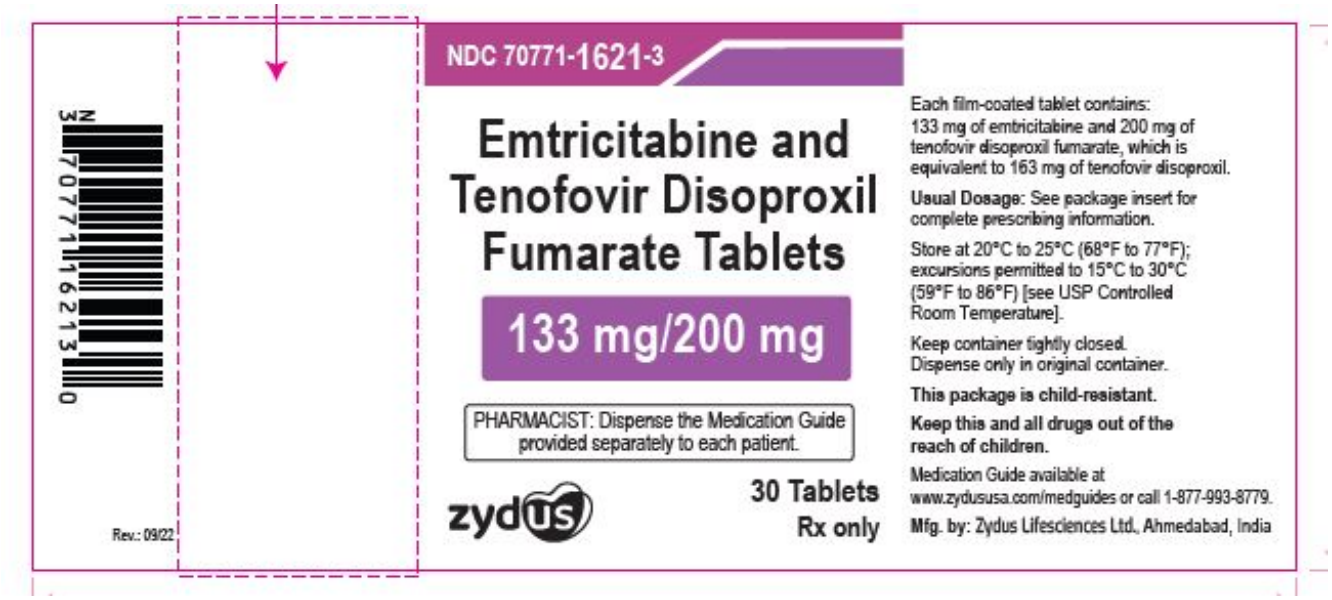
30 tablets

NDC 70771-1621-3

Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 133 mg/200 mg

Rx Only

30 tablets



NDC 70771-1622-3

Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 167 mg/250 mg

Rx Only

30 tablets

NDC 70771-1709-3

Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 200 mg/300 mg

Rx Only

30 tablets

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

emtricitabine and tenofovir disoproxil fumarate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1620
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EMTRICITABINE (UNII: G70B4ETF4S) (EMTRICITABINE - UNII:G70B4ETF4S)	EMTRICITABINE	100 mg
TENOFOVIR DISOPROXIL FUMARATE (UNII: OTT9J7900I) (TENOFOVIR ANHYDROUS - UNII:W4HFE001U5)	TENOFOVIR DISOPROXIL FUMARATE	150 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONOCAPRYLOCAPRATE (UNII: G7515SW10N)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
KAOLIN (UNII: 24H4NWX5CO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	1364
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1620-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	
2	NDC:70771-1620-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	
3	NDC:70771-1620-4	10 in 1 CARTON	07/01/2021	
3	NDC:70771-1620-2	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	ANDA212689	07/01/2021	

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

emtricitabine and tenofovir disoproxil fumarate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1621
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EMTRICITABINE (UNII: G70B4ETF4S) (EMTRICITABINE - UNII:G70B4ETF4S)	EMTRICITABINE	133 mg
TENOFOVIR DISOPROXIL FUMARATE (UNII: OTT9J7900I) (TENOFOVIR ANHYDROUS - UNII:W4HFE001U5)	TENOFOVIR DISOPROXIL FUMARATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONOCAPRYLOCAPRATE (UNII: G7515SW10N)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
KAOLIN (UNII: 24H4NWX5CO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	RECTANGLE	**Size**	16mm
Flavor		**Imprint Code**	1365
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1621-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	
2	NDC:70771-1621-4	10 in 1 CARTON	07/01/2021	
2	NDC:70771-1621-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:70771-1621-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA212689	07/01/2021	

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

emtricitabine and tenofovir disoproxil fumarate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1622
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EMTRICITABINE (UNII: G70B4ETF4S) (EMTRICITABINE - UNII:G70B4ETF4S)	EMTRICITABINE	167 mg
TENOFOVIR DISOPROXIL FUMARATE (UNII: OTT9J7900I) (TENOFOVIR ANHYDROUS - UNII:W4HFE001U5)	TENOFOVIR DISOPROXIL FUMARATE	250 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONOCAPRYLOCAPRATE (UNII: G7515SW10N)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
KAOLIN (UNII: 24H4NWX5CO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (modified capsule)	**Size**	18mm
Flavor		**Imprint Code**	1366
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1622-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	
2	NDC:70771-1622-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2021	
3	NDC:70771-1622-4	10 in 1 CARTON	07/01/2021	
3	NDC:70771-1622-2	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	ANDA212689	07/01/2021	

EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE

emtricitabine and tenofovir disoproxil fumarate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1709
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EMTRICITABINE (UNII: G70B4ETF4S) (EMTRICITABINE - UNII:G70B4ETF4S)	EMTRICITABINE	200 mg
TENOFOVIR DISOPROXIL FUMARATE (UNII: OTT9J7900I) (TENOFOVIR ANHYDROUS - UNII:W4HFE001U5)	TENOFOVIR DISOPROXIL FUMARATE	300 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL MONOCAPRYLOCAPRATE (UNII: G7515SW10N)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
KAOLIN (UNII: 24H4NWX5CO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics

Color	WHITE (off-white)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	1367
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1709-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2021	
2	NDC:70771-1709-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/24/2021	
3	NDC:70771-1709-4	10 in 1 CARTON	03/24/2021	
3	NDC:70771-1709-2	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	ANDA212689	03/24/2021	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1620, 70771-1621, 70771-1622, 70771-1709) , MANUFACTURE(70771-1620, 70771-1621, 70771-1622, 70771-1709)

Revised: 11/2024 Zydus Lifesciences Limited