DEFERASIROX- deferasirox tablet, film coated
Zydus Lifesciences Limited

DEFERASIROX TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1471-3

Deferasirox tablets, 90 mg

30 Tablets

Rx only

NDC 70771-1472-3

Deferasirox tablets, 180 mg

30 Tablets

Rx only

NDC 70771-1473-3

Deferasirox tablets, 360 mg

30 Tablets

Rx only

DEFERASIROX

deferasirox tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1471
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEFERASIROX (UNII: V8G4MOF2V9) (DEFERASIROX - UNII:V8G4MOF2V9)	DEFERASIROX	90 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (off-white)	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	1275
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1471-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2019	
2	NDC:70771-1471-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211383	11/21/2019	

DEFERASIROX

deferasirox tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1473
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEFERASIROX (UNII: V8G4MOF2V9) (DEFERASIROX - UNII:V8G4MOF2V9)	DEFERASIROX	360 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	1277
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1473-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2019	
2	NDC:70771-1473-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211383	11/21/2019	

DEFERASIROX

deferasirox tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1472
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEFERASIROX (UNII: V8G4MOF2V9) (DEFERASIROX - UNII:V8G4MOF2V9)	DEFERASIROX	180 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BLUE (light blue)	**Score**	no score
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	1276
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1472-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	
2	NDC:70771-1472-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211383	06/16/2020	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1471, 70771-1472, 70771-1473) , MANUFACTURE(70771-1471, 70771-1472, 70771-1473)

Revised: 11/2024 Zydus Lifesciences Limited