DEFERASIROX- deferasirox tablet, for suspension
Zydus Lifesciences Limited

Deferasirox Tablets for Oral Suspension

SPL MEDGUIDE

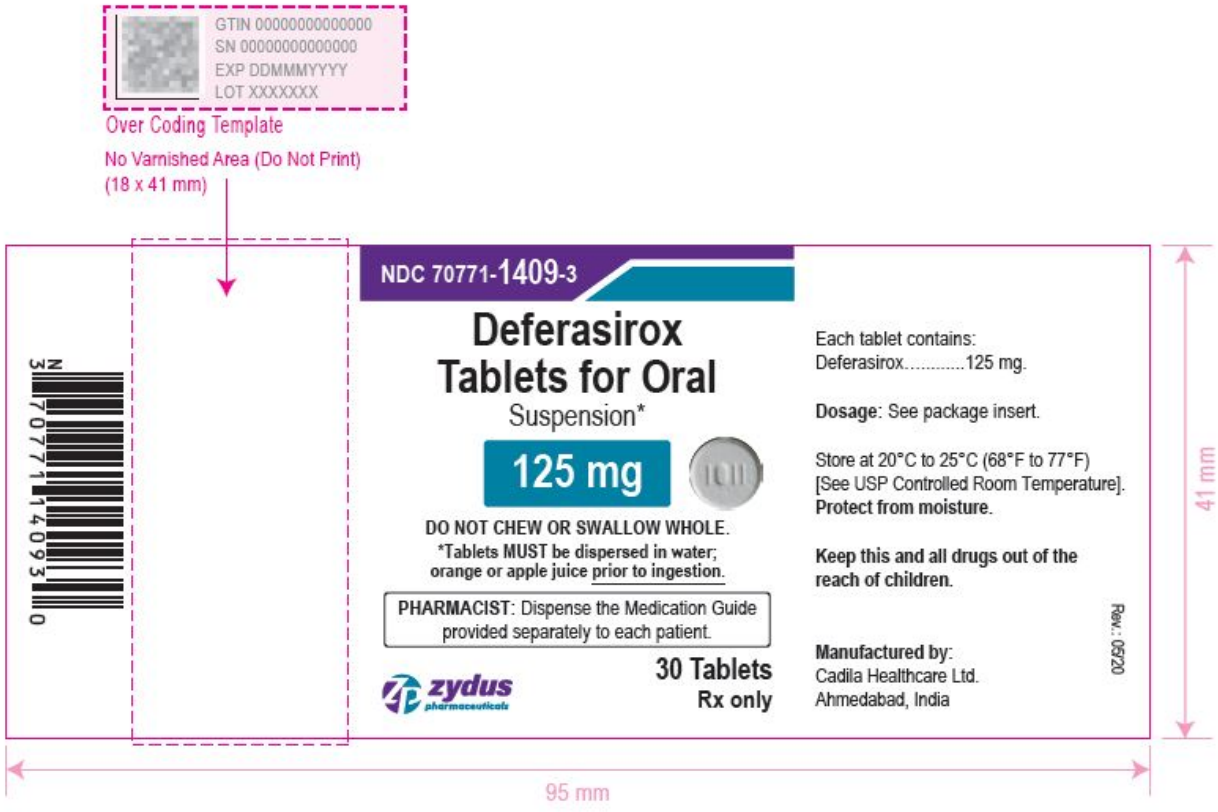
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1409-3

Deferasirox Tablets for Oral Suspension, 125 mg

30 Tablets

Rx only

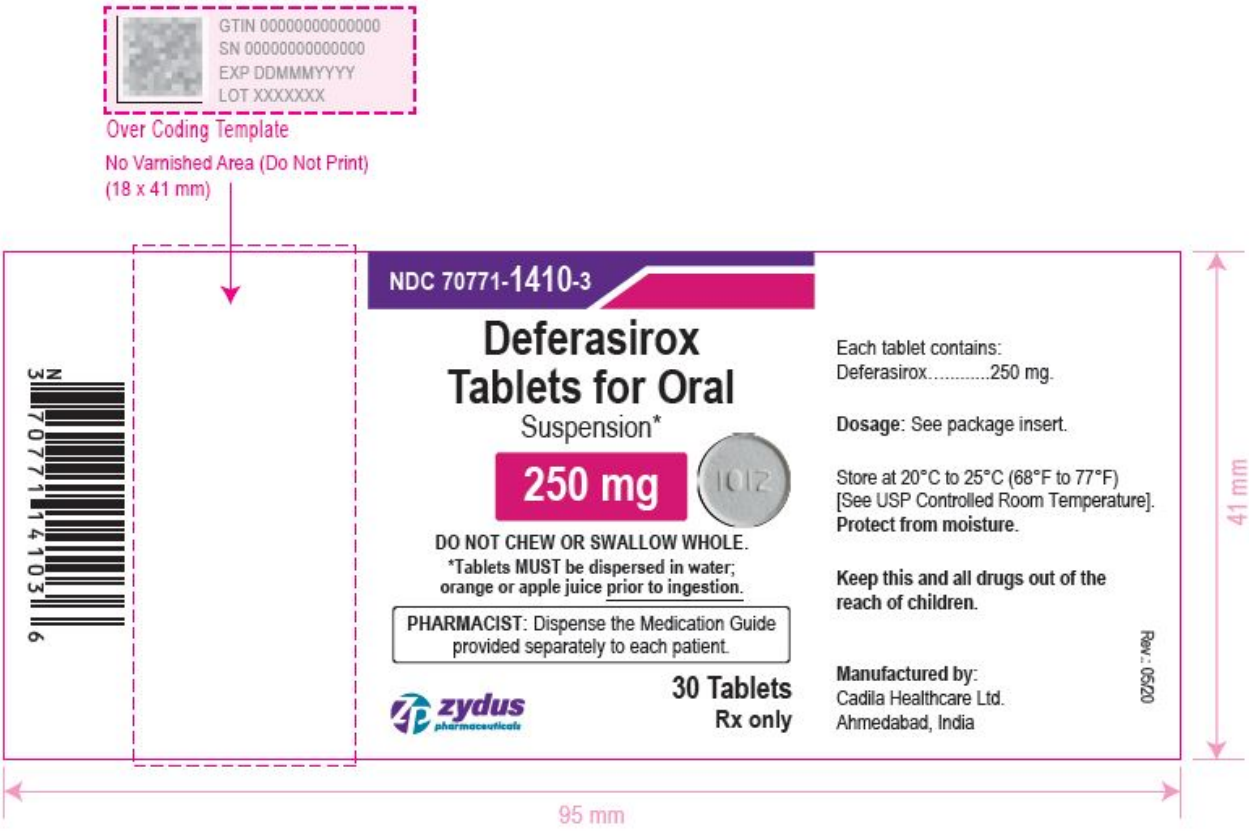


NDC 70771-1410-3

Deferasirox Tablets for Oral Suspension, 250 mg

30 Tablets

Rx only



NDC 70771-1411-3

Deferasirox Tablets for Oral Suspension, 500 mg

30 Tablets

Rx only

DEFERASIROX

deferasirox tablet, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1409
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEFERASIROX (UNII: V8G4MOF2V9) (DEFERASIROX - UNII:V8G4MOF2V9)	DEFERASIROX	125 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	12mm
Flavor		**Imprint Code**	1011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1409-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	
2	NDC:70771-1409-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	
3	NDC:70771-1409-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208882	05/06/2021	

DEFERASIROX

deferasirox tablet, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1410
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEFERASIROX (UNII: V8G4MOF2V9) (DEFERASIROX - UNII:V8G4MOF2V9)	DEFERASIROX	250 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	15mm
Flavor		**Imprint Code**	1012
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1410-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	
2	NDC:70771-1410-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	
3	NDC:70771-1410-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208882	05/06/2021	

DEFERASIROX

deferasirox tablet, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1411
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEFERASIROX (UNII: V8G4MOF2V9) (DEFERASIROX - UNII:V8G4MOF2V9)	DEFERASIROX	500 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	WHITE (WHITE TO OFF WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	18mm
Flavor		**Imprint Code**	1013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1411-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	
2	NDC:70771-1411-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	
3	NDC:70771-1411-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/06/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208882	05/06/2021	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (863362789)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1409, 70771-1410, 70771-1411) , MANUFACTURE(70771-1409, 70771-1410, 70771-1411)

Revised: 11/2024 Zydus Lifesciences Limited