

**DEFERASIROX- deferasirox tablet, for suspension**  
**Zydus Lifesciences Limited**

**Deferasirox Tablets for Oral Suspension**

**SPL MEDGUIDE**

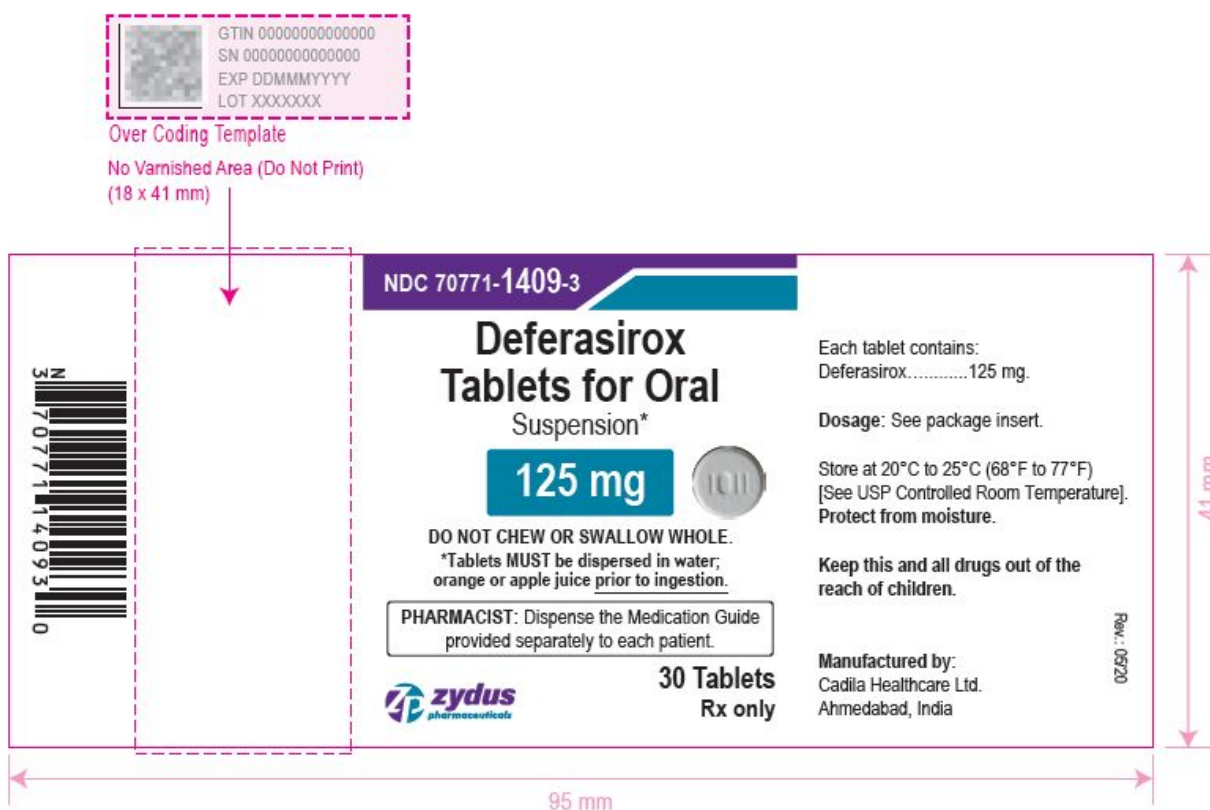
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

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



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1410-3

# Deferasirox Tablets for Oral Suspension\*

**250 mg** 

**DO NOT CHEW OR SWALLOW WHOLE.**  
\*Tablets **MUST** be dispersed in water;  
orange or apple juice prior to ingestion.

**PHARMACIST:** Dispense the Medication Guide  
provided separately to each patient.

 **zydus**  
pharmaceuticals

**30 Tablets**  
Rx only

Each tablet contains:  
Deferasirox.....250 mg.

**Dosage:** See package insert.

Store at 20°C to 25°C (68°F to 77°F)  
[See USP Controlled Room Temperature].  
**Protect from moisture.**

**Keep this and all drugs out of the  
reach of children.**

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 05/20

3  
N  
70771  
4103  
6

95 mm

41 mm

NDC 70771-1411-3

Deferasirox Tablets for Oral Suspension, 500 mg

30 Tablets

Rx only



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 50.5 mm)

NDC 70771-1411-3

**Deferasirox Tablets for Oral Suspension\***

**500 mg**

1013

DO NOT CHEW OR SWALLOW WHOLE.  
\*Tablets **MUST** be dispersed in water; orange or apple juice prior to ingestion.

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

zydus pharmaceuticals

30 Tablets Rx only

Each tablet contains:  
Deferasirox.....500 mg.

Dosage: See package insert.

Store at 20°C to 25°C (68°F to 77°F)  
[See USP Controlled Room Temperature].  
Protect from moisture.

Keep this and all drugs out of the reach of children.

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 05/20

97 mm

50.5 mm

## DEFERASIROX

deferasirox tablet, for suspension

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1409
<b>Route of Administration</b>	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)	
CROSPVIDONE (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

<b>Color</b>	WHITE (WHITE TO OFF WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	1011
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1410
<b>Route of Administration</b>	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)	
CROSPVIDONE (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

<b>Color</b>	WHITE (WHITE TO OFF WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	15mm
<b>Flavor</b>		<b>Imprint Code</b>	1012
<b>Contains</b>			

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1411
<b>Route of Administration</b>	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)	
CROSPVIDONE (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

<b>Color</b>	WHITE (WHITE TO OFF WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	1013
<b>Contains</b>			

### 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: 9/2023

Zydus Lifesciences Limited