

**DOXYCYCLINE HYCLATE- doxycycline hyclate tablet, delayed release**  
**Zydus Lifesciences Limited**

**Doxycycline Hyclate Delayed-release Tablets, USP**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1587-6 in bottle of 60 tablets

Doxycycline Hyclate Delayed-release Tablets USP, 75 mg

Rx only

60 tablets



NDC 70771-1588-6 in bottle of 60 tablets

Doxycycline Hyclate Delayed-release Tablets USP, 100 mg

Rx only

60 tablets

GTIN 00000000000000  
SN 00000000000000  
EXP DDMMYYYY  
LOT XXXXXXX

Over Coding Template

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

The image shows a rectangular product label with a width of 97 mm and a height of 50.5 mm. At the top left, there is a purple and green header with the NDC number 70771-1588-6. The main title is 'Doxycycline Hyclate Delayed-Release Tablets, USP' in large black font. Below the title is a green box containing '100 mg\*'. To the left of the main text is a vertical barcode with the numbers 52707711588617 printed vertically. Below the main title is the instruction 'Do not chew or crush tablets.' At the bottom left is the Zydus logo. At the bottom center, it says '60 Tablets Rx only'. At the bottom right, it lists the manufacturer: 'Manufactured by: Cadila Healthcare Ltd. Matoda, Ahmedabad, India'. On the far right edge, there is a vertical reference number 'Ref: 05/20'. On the right side, there is a vertical dimension line indicating a height of 50.5 mm. At the bottom, there is a horizontal dimension line indicating a width of 97 mm. A dashed box on the left side of the label indicates a 'No Varnished Area (Do Not Print)' of 18 x 50.5 mm.

NDC 70771-1589-6 in bottle of 60 tablets

Doxycycline Hyclate Delayed-release Tablets USP, 150 mg

Rx only

60 tablets



Over Coding Template

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

**NDC 70771-1589-6**

**Doxycycline Hyclate  
Delayed-Release  
Tablets, USP**

**150 mg\***

Do not chew or crush tablets.

**zydus** pharmaceuticals

**60 Tablets  
Rx only**

Manufactured by:  
Cadila Healthcare Ltd.  
Matoda, Ahmedabad, India

Rev. 05/20

\*Each tablet contains specially coated pellets of doxycycline hyclate, USP equivalent to 150 mg of doxycycline.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25° C (68° to 77° F); excursions permitted to 15° to 30° C (59° to 86° F) [see USP Controlled Room Temperature]. Dispense in a tight, light-resistant container (USP).

**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

Dimensions: 97 mm (width), 50.5 mm (height)

## DOXYCYCLINE HYCLATE

doxycycline hyclate tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1587
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOXYCYCLINE HYCLATE</b> (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	75 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST)</b> (UNII: 87Y6436BKR)	

<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	70;8
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1587-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
2	NDC:70771-1587-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
3	NDC:70771-1587-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
4	NDC:70771-1587-4	10 in 1 CARTON	12/21/2018	
4	NDC:70771-1587-2	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	ANDA206772	12/21/2018	

## DOXYCYCLINE HYCLATE

doxycycline hyclate tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1588
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOXYCYCLINE HYCLATE</b> (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS -	DOXYCYCLINE	100 mg

UNII:334895S862)

ANHYDROUS

100 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST)</b> (UNII: 87Y6436BKR)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

**Product Characteristics**

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	70;9
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1588-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
2	NDC:70771-1588-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
3	NDC:70771-1588-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
4	NDC:70771-1588-4	10 in 1 CARTON	12/21/2018	
4	NDC:70771-1588-2	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	ANDA206772	12/21/2018	

**DOXYCYCLINE HYCLATE**

doxycycline hyclate tablet, delayed release

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1589
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DOXYCYCLINE HYCLATE</b> (UNII: 19XTS3T51U) (DOXYCYCLINE ANHYDROUS - UNII:334895S862)	DOXYCYCLINE ANHYDROUS	150 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSE PHTHALATE (24% PHTHALATE, 55 CST)</b> (UNII: 87Y6436BKR)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	3 pieces
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	7;1;0
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70771-1589-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
2	NDC:70771-1589-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
3	NDC:70771-1589-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2018	
4	NDC:70771-1589-4	10 in 1 CARTON	12/21/2018	
4	NDC:70771-1589-2	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	ANDA206772	12/21/2018	

**Labeler** - Zydus Lifesciences Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1587, 70771-1588, 70771-1589) , MANUFACTURE(70771-1587, 70771-1588, 70771-1589)

Revised: 11/2024

Zydus Lifesciences Limited