

**DOXYCYCLINE HYCLATE - doxycycline hyclate capsule**  
**Zydus Lifesciences Limited**

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**Doxycycline hyclate capsules**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1358-7

Doxycycline hyclate capsules, 50 mg

Rx only

50 capsules



NDC 70771-1359-7

Doxycycline hyclate capsules, 100 mg

Rx only

50 capsules

NDC 70771-1359-7



# Doxycycline Hyclate

## Capsules, USP

100 mg\*



\*Each capsule contains:  
Doxycycline Hyclate, USP equivalent to  
100 mg of Doxycycline.

**Dosage and uses:** See accompanying  
prescribing information.

Store at 20° to 25°C (68° to 77°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**



**50 CAPSULES**  
Rx only

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

Rev.: 06/18

## DOXYCYCLINE HYCLATE

doxycycline hyclate capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1358
<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	50 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE (BLUE) , WHITE (WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	CHL;D75
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1358-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
2	NDC:70771-1358-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
3	NDC:70771-1358-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
4	NDC:70771-1358-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
5	NDC:70771-1358-4	10 in 1 CARTON	09/12/2018	
5	NDC:70771-1358-2	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	ANDA207774	09/12/2018	

## DOXYCYCLINE HYCLATE

doxycycline hyclate capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1359
<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	100 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B710)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	BLUE (LIGHT BLUE) , BLUE (LIGHT BLUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	CHL;D76
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1359-7	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
2	NDC:70771-1359-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
3	NDC:70771-1359-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
4	NDC:70771-1359-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/12/2018	
5	NDC:70771-1359-4	10 in 1 CARTON	09/12/2018	
5	NDC:70771-1359-2	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	ANDA207774	09/12/2018	

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

**Registrant** - Zydus Lifesciences Limited (863362789)

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1358, 70771-1359) , MANUFACTURE(70771-1358, 70771-1359)

Revised: 11/2022

Zydus Lifesciences Limited