

# CLINDAMYCIN HYDROCHLORIDE - clindamycin hydrochloride capsule, gelatin coated

Zydus Lifesciences Limited

## Clindamycin Hydrochloride Capsules, USP

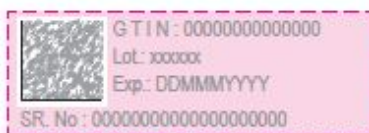
### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1136-1 in bottle of 100 Capsules

Clindamycin Hydrochloride Capsules USP, 75 mg

Rx only

100 Capsules



Over Coding Template

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

NDC 70771-1136-1

**Clindamycin Hydrochloride Capsules, USP**

**75 mg\***

3 N  
7077111361  
3

\*Each capsule contains :  
Clindamycin hydrochloride USP  
equivalent to clindamycin.....75 mg

**Usual adult dosage** -150 mg four times daily. See package insert for complete prescribing information.

Store at 20°-25°C (68°-77°F)  
[see USP Controlled Room Temperature].

Dispense in tight, light-resistant containers as described in the USP.

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

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

100 Capsules  
Rx only

zydus  
pharmaceuticals

Rev: 10/18

NDC 70771-1137-1 in bottle of 100 Capsules

Clindamycin Hydrochloride Capsules USP, 150 mg

Rx only

100 Capsules

GTIN: 00000000000000  
Lot: xxxxxx  
Exp: DDMMYYYY  
SR, No: 000000000000000000

Over Coding Template

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

The image shows a product label for Clindamycin Hydrochloride Capsules, USP, 150 mg\*. The label is white with a purple header and a purple box for the strength. On the left, there is a barcode with the number 3 N 707711113712 printed vertically. The main text on the label includes the NDC number 70771-1137-1, the product name, the strength, and the manufacturer's name, Zydus Pharmaceuticals. The label also contains dosage information, storage instructions, and a warning to keep the drug out of children's reach. The manufacturer's name and address are listed at the bottom right.

**NDC 70771-1137-1**

# Clindamycin Hydrochloride Capsules, USP

**150 mg\***

**100 Capsules**  
Rx only

**zydus**  
pharmaceuticals

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

**Rev: 10/18**

\*Each capsule contains :  
Clindamycin hydrochloride USP  
equivalent to clindamycin.....150 mg

Usual adult dosage -150 mg four times  
daily. See package insert for complete  
prescribing information.

Store at 20°-25°C (68°-77°F)  
[see USP Controlled Room Temperature].

Dispense in tight, light-resistant  
containers as described in the USP.

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

3 N  
707711113712


NDC 70771-1183-1 in bottle of 100 Capsules  
Clindamycin Hydrochloride Capsules USP, 300 mg  
Rx only  
100 Capsules

GTIN : 00000000000000  
 Lot: xxxxxx  
 Exp.: DDMMYYYY  
 SR. No : 000000000000000000

Over Coding Template

No Varnished Area (Do Not Print)

(18 x 50.5 mm)




N  
70771111831  
1

**NDC 70771-1183-1**

# Clindamycin Hydrochloride Capsules, USP

**300 mg\***

**100 Capsules**  
Rx only



\*Each capsule contains :  
Clindamycin hydrochloride USP  
equivalent to clindamycin.....300 mg

Usual adult dosage -300 mg every  
six hours. See package insert for complete  
prescribing information.

Store at 20°-25°C (68°-77°F)  
[see USP Controlled Room Temperature].

Dispense in tight, light-resistant  
containers as described in the USP.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev : 10/18

## CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1136
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CLINDAMYCIN HYDROCHLORIDE</b> (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	75 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	

<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE (BLUE (CAP)) , BLUE (BLUE (BODY))	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	Z;89
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1136-8	16 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
2	NDC:70771-1136-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
3	NDC:70771-1136-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065217	11/17/2017	

## CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1137
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CLINDAMYCIN HYDROCHLORIDE</b> (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	150 mg

### Inactive Ingredients

Ingredient Name	Strength
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<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	BLUE (BLUE (CAP)) , BLUE (BLUE (BODY))	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	Z;90
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1137-8	16 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
2	NDC:70771-1137-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
3	NDC:70771-1137-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065217	11/23/2017	

## CLINDAMYCIN HYDROCHLORIDE

clindamycin hydrochloride capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1183
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CLINDAMYCIN HYDROCHLORIDE</b> (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	300 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

Color	BLUE (BLUE (CAP)) , BLUE (BLUE (BODY))	Score	no score
Shape	CAPSULE (CAPSULE)	Size	21mm
Flavor		Imprint Code	Z;91
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1183-8	16 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
2	NDC:70771-1183-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	
3	NDC:70771-1183-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065217	11/23/2017	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1136, 70771-1137, 70771-1183) , MANUFACTURE(70771-1136, 70771-1137, 70771-1183)