

**DULOXETINE- duloxetine capsule, delayed release**  
**Zydus Lifesciences Limited**

**DULOXETINE DELAYED-RELEASE CAPSULES**

**Manufactured by:**

Cadila Healthcare Ltd.

India.

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1344-3

Duloxetine Delayed-release Capsules, 20mg

30 Capsules

Rx only




Over Coding Template

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


NDC 70771-1344-3

**Duloxetine  
Delayed-release  
Capsules, USP**

**20 mg** 

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

**30 Capsules**  
**Rx only**

  
N  
70771113443  
4

Each delayed-release capsule contains 22.4 mg of duloxetine hydrochloride, USP equivalent to duloxetine.....20 mg

**Usual Dosage:** See package insert for complete prescribing information.

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

Dispense in a tight container.

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

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

Rev: 05/18

NDC 70771-1345-3

Duloxetine Delayed-release Capsules, 30mg

30 Capsules

Rx only




Over Coding Template

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


**NDC 70771-1345-3**

**Duloxetine  
Delayed-release  
Capsules, USP**

**30 mg** 

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

**30 Capsules**  
**Rx only**



Each delayed-release capsule contains 33.7 mg of duloxetine hydrochloride, USP equivalent to duloxetine .....30 mg

**Usual Dosage:** See package insert for complete prescribing information.

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

Dispense in a tight container.

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

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

Rev.: 05/18

3  
N  
7077113453  
3

NDC 70771-1346-3

Duloxetine Delayed-release Capsules, 60mg

30 Capsules

Rx only

GTIN : 00000000000000  
 Lot : xxxxxx  
 Exp : MMM/YY  
 SR. No : 00000000000000000000

Over Coding Template

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



**NDC 70771-1346-3**

## Duloxetine Delayed-release Capsules, USP

**60 mg** 

**30 Capsules**  
Rx only

Each delayed-release capsule contains 67.3 mg of duloxetine hydrochloride, USP equivalent to duloxetine.....60 mg

**Usual Dosage:** See package insert for complete prescribing information.

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

Dispense in a tight container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev : 05/18

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



## DULOXETINE

duloxetine capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1344
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DULOXETINE HYDROCHLORIDE</b> (UNII: 9044SC542W) (DULOXETINE - UNII:O5TNM5N07U)	DULOXETINE	20 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	

<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>GELATIN</b> (UNII: 2G86QN327L)
<b>HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)</b> (UNII: G4U024CQK6)
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SHELLAC</b> (UNII: 46N107B710)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)
<b>SUCROSE</b> (UNII: C151H8M554)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)

### Product Characteristics

<b>Color</b>	GREEN (GREEN) , WHITE (WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	385;20;mg
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1344-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
2	NDC:70771-1344-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
3	NDC:70771-1344-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
4	NDC:70771-1344-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090728	05/27/2014	

## DULOXETINE

duloxetine capsule, delayed release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1345
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DULOXETINE HYDROCHLORIDE</b> (UNII: 9044SC542W) (DULOXETINE - UNII:O5TNM5N07U)	DULOXETINE	30 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)</b> (UNII: G4U024CQK6)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

**Product Characteristics**

<b>Color</b>	BLUE (BLUE) , GREEN (GREEN)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	386;30;mg
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1345-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
2	NDC:70771-1345-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
3	NDC:70771-1345-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090728	05/27/2014	

## DULOXETINE

duloxetine capsule, delayed release

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1346
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DULOXETINE HYDROCHLORIDE</b> (UNII: 9044SC542W) (DULOXETINE - UNII:O5TNM5N07U)	DULOXETINE	60 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>HYPROMELLOSE PHTHALATE (31% PHTHALATE, 40 CST)</b> (UNII: G4U024CQK6)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

### Product Characteristics

Color	BLUE (BLUE) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	387;60;mg
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1346-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
2	NDC:70771-1346-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2014	
3	NDC:70771-1346-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	04/06/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090728	05/27/2014	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1344, 70771-1345, 70771-1346) , MANUFACTURE(70771-1344, 70771-1345, 70771-1346)

Revised: 9/2023

Zydus Lifesciences Limited