

**OLANZAPINE- olanzapine tablet, film coated**  
**Zydus Lifesciences Limited**

**OLANZAPINE Tablets**

**SPL MEDGUIDE**

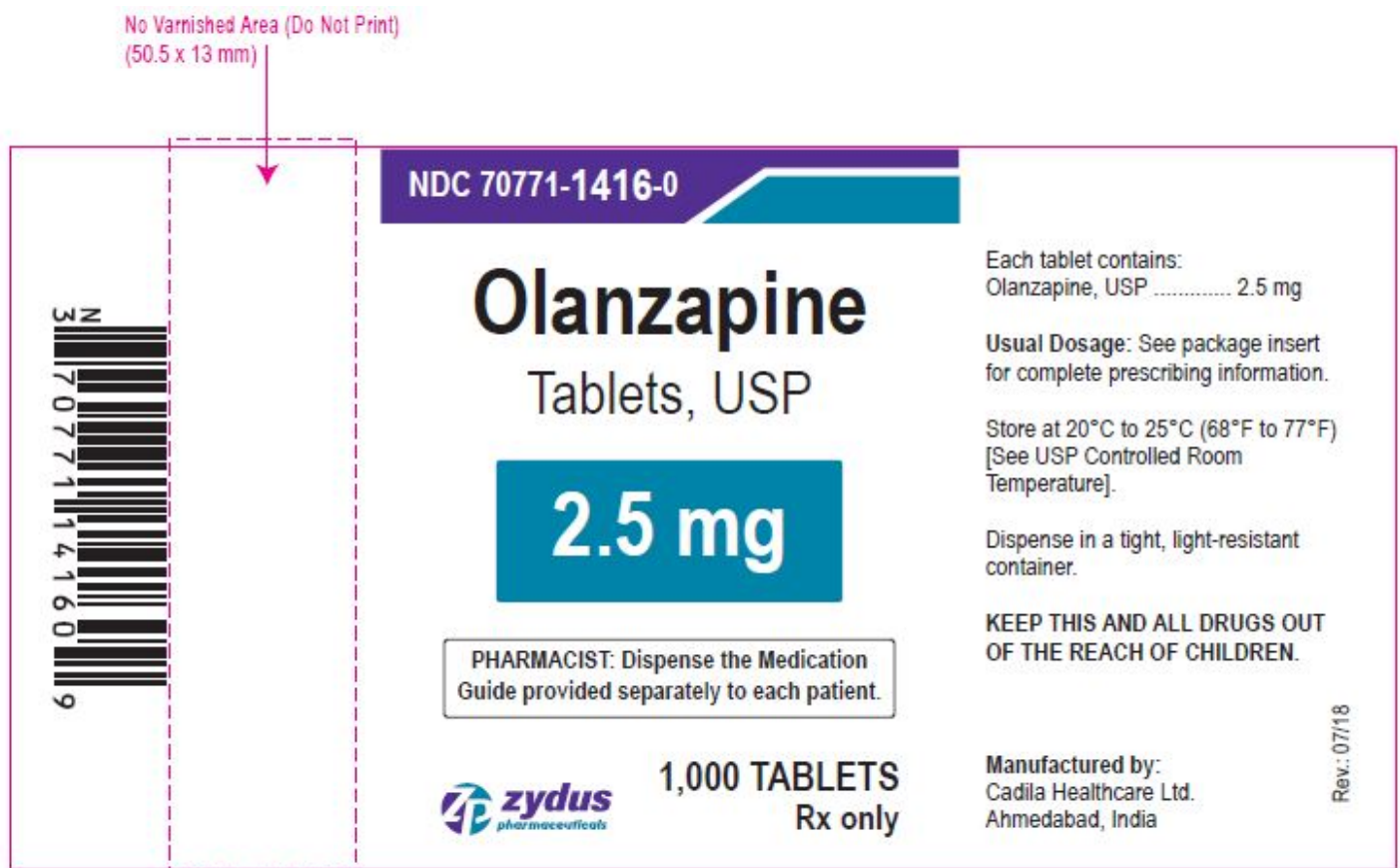
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1416-0 in bottle of 1,000 tablets

Olanzapine Tablets USP, 2.5 mg

Rx only

1,000 tablets



NDC 70771-1417-0 in bottle of 1,000 tablets

Olanzapine Tablets USP, 5 mg

Rx only

1,000 tablets

No Varnished Area (Do Not Print)  
(50.5 x 13 mm)

**NDC 70771-1417-0**

# Olanzapine

Tablets, USP

**5 mg**

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

**1,000 TABLETS**  
Rx only

Each tablet contains:  
Olanzapine, USP ..... 5 mg

Usual Dosage: See package insert for complete prescribing information.

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

Dispense in a tight, light-resistant container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev.: 07/18

NDC 70771-1418-0 in bottle of 1,000 tablets

Olanzapine Tablets USP, 7.5 mg

Rx only

1,000 tablets

No Varnished Area (Do Not Print)  
(50.5 x 13 mm)

**NDC 70771-1418-0**

# Olanzapine

Tablets, USP

## 7.5 mg

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

**1,000 TABLETS**  
Rx only

**zydus**  
pharmaceuticals

Each tablet contains:  
Olanzapine, USP ..... 7.5 mg

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

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

Dispense in a tight, light-resistant container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev.: 07/18

NDC 70771-1419-0 in bottle of 1,000 tablets

Olanzapine Tablets USP, 10 mg

Rx only

1,000 tablets

No Varnished Area (Do Not Print)  
(50.5 x 13 mm)

NDC 70771-1419-0

# Olanzapine

Tablets, USP

**10 mg**

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

**1,000 TABLETS**  
Rx only

Each tablet contains:  
Olanzapine, USP ..... 10 mg

Usual Dosage: See package insert for complete prescribing information.

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

Dispense in a tight, light-resistant container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 07/18

NDC 70771-1420-0 in bottle of 1,000 tablets

Olanzapine Tablets USP, 15 mg

Rx only

1,000 tablets

No Varnished Area (Do Not Print)  
(16 x 60 mm)

**NDC 70771-1420-0**

# Olanzapine

Tablets, USP

## 15 mg

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

**zydus** pharmaceuticals

**1,000 TABLETS**  
Rx only

Each tablet contains:  
Olanzapine, USP ..... 15 mg

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

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

Dispense in a tight, light-resistant container.

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

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

Rev.: 07/18

NDC 70771-1421-0 in bottle of 1,000 tablets


Olanzapine Tablets USP, 20 mg

Rx only

1,000 tablets

No Varnished Area (Do Not Print)  
(70 x 16 mm)

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NDC 70771-1421-0

# Olanzapine

## Tablets, USP

20 mg

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



**1,000 TABLETS**

**Rx only**

Each tablet contains:  
Olanzapine, USP ..... 20 mg

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

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

Dispense in a tight, light-resistant container.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 07/18

## OLANZAPINE

olanzapine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1416
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OLANZAPINE</b> (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	2.5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	



## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF28
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1416-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
2	NDC:70771-1416-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
3	NDC:70771-1416-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
4	NDC:70771-1416-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
5	NDC:70771-1416-4	10 in 1 CARTON	01/03/2019	
5	NDC:70771-1416-2	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	ANDA090459	01/03/2019	

## OLANZAPINE

olanzapine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1417
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OLANZAPINE</b> (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	

<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF29
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1417-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
2	NDC:70771-1417-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
3	NDC:70771-1417-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
4	NDC:70771-1417-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
5	NDC:70771-1417-4	10 in 1 CARTON	01/03/2019	
5	NDC:70771-1417-2	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	ANDA090459	01/03/2019	

## OLANZAPINE

olanzapine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1418
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OLANZAPINE</b> (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	7.5 mg



## Inactive Ingredients

Ingredient Name	Strength
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF30
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1418-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
2	NDC:70771-1418-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
3	NDC:70771-1418-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
4	NDC:70771-1418-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
5	NDC:70771-1418-4	10 in 1 CARTON	01/03/2019	
5	NDC:70771-1418-2	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	ANDA090459	01/03/2019	

## OLANZAPINE

olanzapine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1419
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OLANZAPINE</b> (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	10 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CROSPROVIDONE</b> (UNII: 2S7830E561)	

**Product Characteristics**

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF31
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1419-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
2	NDC:70771-1419-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
3	NDC:70771-1419-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
4	NDC:70771-1419-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
5	NDC:70771-1419-4	10 in 1 CARTON	01/03/2019	
5	NDC:70771-1419-2	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	ANDA090459	01/03/2019	

**OLANZAPINE**

olanzapine tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1420
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OLANZAPINE</b> (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	15 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF-WHITE)	<b>Score</b>	no score
<b>Shape</b>	OVAL (ELLIPTICAL-SHAPED)	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	ZF32
<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:70771-1420-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
2	NDC:70771-1420-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
3	NDC:70771-1420-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
4	NDC:70771-1420-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
5	NDC:70771-1420-4	10 in 1 CARTON	01/03/2019	
5	NDC:70771-1420-2	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	ANDA090459	01/03/2019	

## OLANZAPINE

olanzapine tablet, film coated

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1421
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLANZAPINE (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	20 mg

### Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (ELLIPTICAL-SHAPED)	Size	14mm
Flavor		Imprint Code	ZF33
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1421-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
2	NDC:70771-1421-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
3	NDC:70771-1421-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
4	NDC:70771-1421-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2019	
5	NDC:70771-	10 in 1 CARTON	01/03/2019	

5	1421-4	10 in 1 CARTON	01/03/2019	
5	NDC:70771-1421-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA090459		01/03/2019	

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

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1416, 70771-1417, 70771-1418, 70771-1419, 70771-1420, 70771-1421) , MANUFACTURE(70771-1416, 70771-1417, 70771-1418, 70771-1419, 70771-1420, 70771-1421)

Revised: 12/2024

Zydus Lifesciences Limited