

OLANZAPINE- olanzapine tablet, film coated
Zydus Lifesciences Limited

OLANZAPINE Tablets

SPL MEDGUIDE

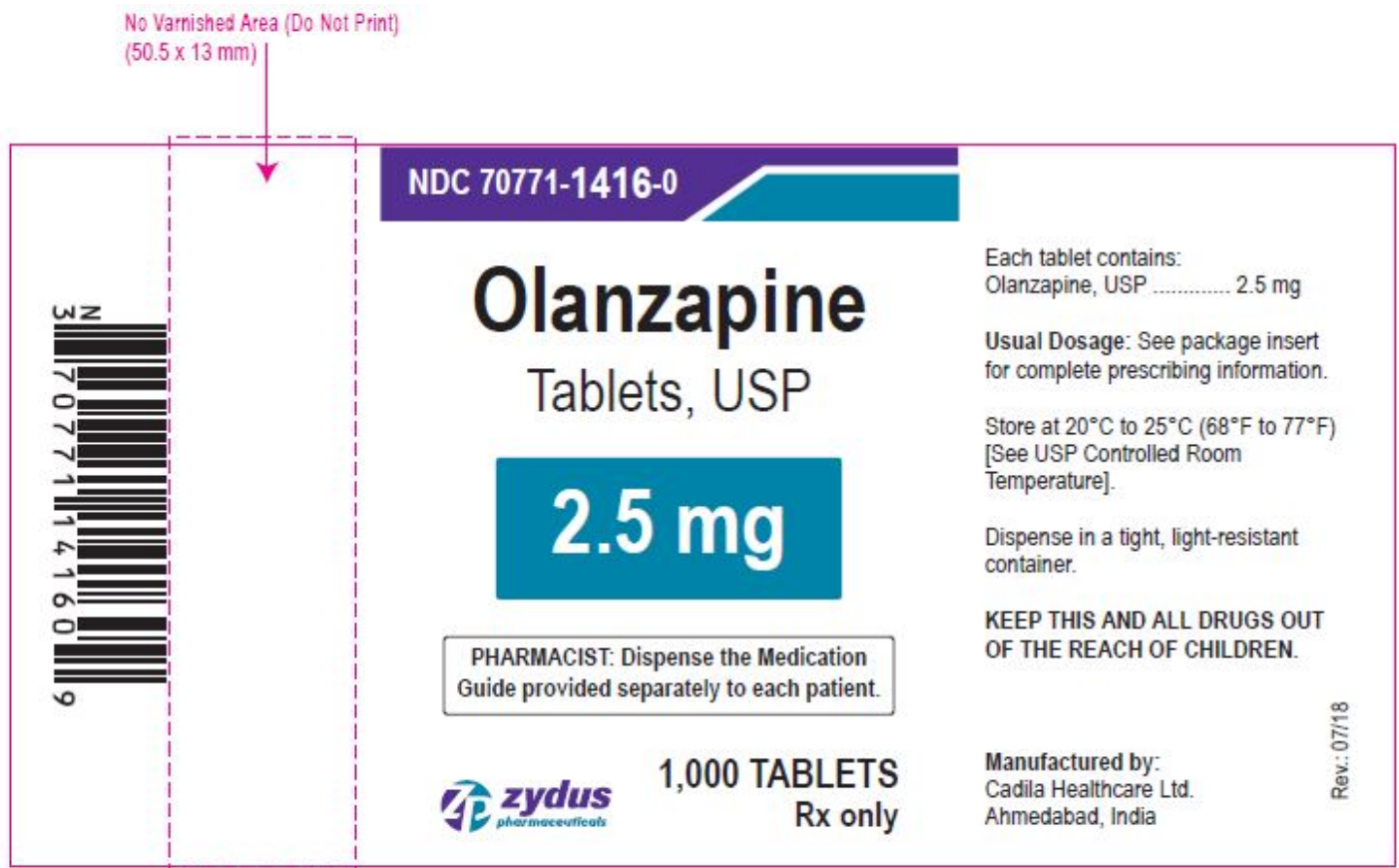
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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.

zydus
pharmaceuticals

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.

zydus pharmaceuticals

1,000 TABLETS
Rx only

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.

zydus
pharmaceuticals

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLANZAPINE (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (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	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZF28
Contains			

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLANZAPINE (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (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	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZF29
Contains			

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLANZAPINE (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	7.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPROVIDONE (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	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	ZF30
Contains			

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLANZAPINE (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
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)	
CROSPROVIDONE (UNII: 2S7830E561)	

Product Characteristics

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

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLANZAPINE (UNII: N7U69T4SZR) (OLANZAPINE - UNII:N7U69T4SZR)	OLANZAPINE	15 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	12mm
Flavor		Imprint Code	ZF32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA090459		01/03/2019	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
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: 9/2023

Zydus Lifesciences Limited