

OLANZAPINE- olanzapine tablet, orally disintegrating
Zydus Lifesciences Limited

Olanzapine Orally Disintegrating Tablets

SPL MEDGUIDE

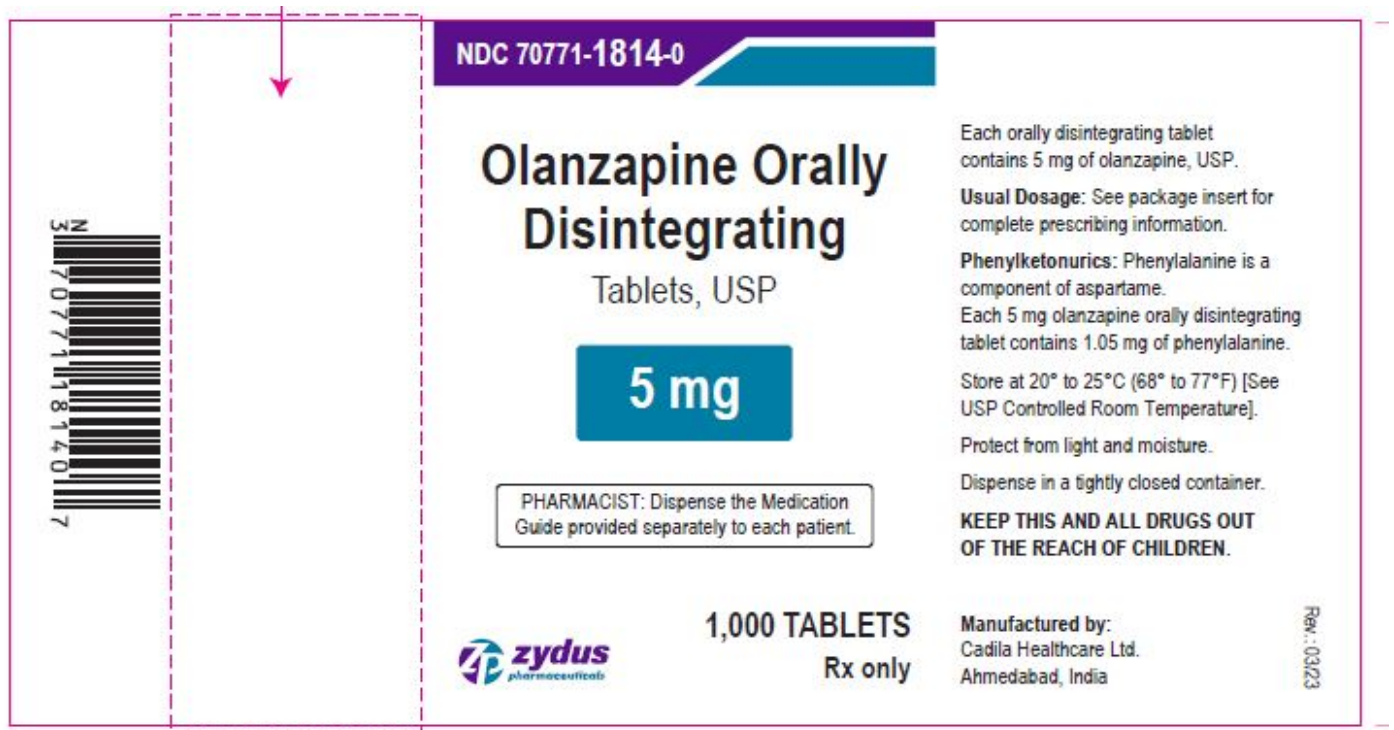
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1814-0

Olanzapine Orally Disintegrating Tablets USP, 5 mg

Rx only

1,000 tablets



NDC 70771-1815-0

Olanzapine Orally Disintegrating Tablets USP, 10 mg

Rx only

1,000 tablets

NDC 70771-1815-0

Olanzapine Orally Disintegrating Tablets, USP

10 mg

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

1,000 TABLETS
Rx only

zydus pharmaceuticals

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 03/23

Each orally disintegrating tablet contains 10 mg of olanzapine, USP.

Usual Dosage: See package insert for complete prescribing information.

Phenylketonurics: Phenylalanine is a component of aspartame. Each 10 mg olanzapine orally disintegrating tablet contains 2.11 mg of phenylalanine.

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

Protect from light and moisture.

Dispense in a tightly closed container.

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

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NDC 70771-1816-0

Olanzapine Orally Disintegrating Tablets USP, 15 mg

Rx only

1,000 tablets

NDC 70771-1816-0

Olanzapine Orally Disintegrating Tablets, USP

15 mg

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

1,000 TABLETS
Rx only

zydus pharmaceuticals

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 03/23

Each orally disintegrating tablet contains 15 mg of olanzapine, USP.

Usual Dosage: See package insert for complete prescribing information.

Phenylketonurics: Phenylalanine is a component of aspartame. Each 15 mg olanzapine orally disintegrating tablet contains 3.16 mg of phenylalanine.

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

Protect from light and moisture.

Dispense in a tightly closed container.

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

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NDC 70771-1817-0

Olanzapine Orally Disintegrating Tablets USP, 20 mg

Rx only

1,000 tablets



NDC 70771-1817-0

Olanzapine Orally Disintegrating Tablets, USP

20 mg

1,000 TABLETS
Rx only



Each orally disintegrating tablet contains 20 mg of olanzapine, USP.

Usual Dosage: See package insert for complete prescribing information.

Phenylketonurics: Phenylalanine is a component of aspartame. Each 20 mg olanzapine orally disintegrating tablet contains 4.22 mg of phenylalanine.

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

Protect from light and moisture.

Dispense in a tightly closed container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 03/23

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

OLANZAPINE

olanzapine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1814
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
ASPARTAME (UNII: Z0H242BBR1)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ORANGE (UNII: 5EVU04N5QU)	
CROSPVIDONE (UNII: 2S7830E561)	

Product Characteristics

Color	YELLOW (Light Yellow toYellow)	Score	no score
Shape	ROUND (round)	Size	6mm
Flavor	ORANGE (orange)	Imprint Code	516
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1814-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
2	NDC:70771-1814-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
3	NDC:70771-1814-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
4	NDC:70771-1814-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
5	NDC:70771-1814-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202889	01/18/2025	

OLANZAPINE

olanzapine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1815
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
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ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPROVIDONE (UNII: 2S7830E561)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
ORANGE (UNII: 5EVU04N5QU)	

Product Characteristics

Color	YELLOW (Light Yellow to Yellow)	Score	no score
Shape	ROUND (round)	Size	7mm
Flavor	ORANGE (orange)	Imprint Code	517
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1815-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
2	NDC:70771-1815-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
3	NDC:70771-1815-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
4	NDC:70771-1815-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
5	NDC:70771-1815-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202889	01/18/2025	

OLANZAPINE

olanzapine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1816
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
ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
ORANGE (UNII: 5EVU04N5QU)	

Product Characteristics

Color	YELLOW (Light Yellow to Yellow)	Score	no score
Shape	ROUND (round)	Size	9mm
Flavor	ORANGE (orange)	Imprint Code	518
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1816-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
2	NDC:70771-1816-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
3	NDC:70771-1816-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
4	NDC:70771-1816-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
5	NDC:70771-1816-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202889	01/18/2025	

OLANZAPINE

olanzapine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1817
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
ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPVIDONE (UNII: 2S7830E561)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
ORANGE (UNII: 5EVU04N5QU)	

Product Characteristics

Color	YELLOW (Light Yellow to Yellow)	Score	no score
Shape	ROUND (round)	Size	10mm
Flavor	ORANGE (orange)	Imprint Code	519
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1817-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
2	NDC:70771-1817-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
3	NDC:70771-1817-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
4	NDC:70771-1817-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	
5	NDC:70771-1817-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/18/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202889	01/18/2025	

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

Name	Address	ID/FEI	Business Operations
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Zydu Lifesciences Limited		918596198	ANALYSIS(70771-1814, 70771-1815, 70771-1816, 70771-1817) , MANUFACTURE(70771-1814, 70771-1815, 70771-1816, 70771-1817)
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Revised: 12/2024

Zydu Lifesciences Limited