OLANZAPINE- olanzapine tablet, orally disintegrating
Zydus Lifesciences Limited

Olanzapine Orally Disintegrating Tablets

SPL MEDGUIDE

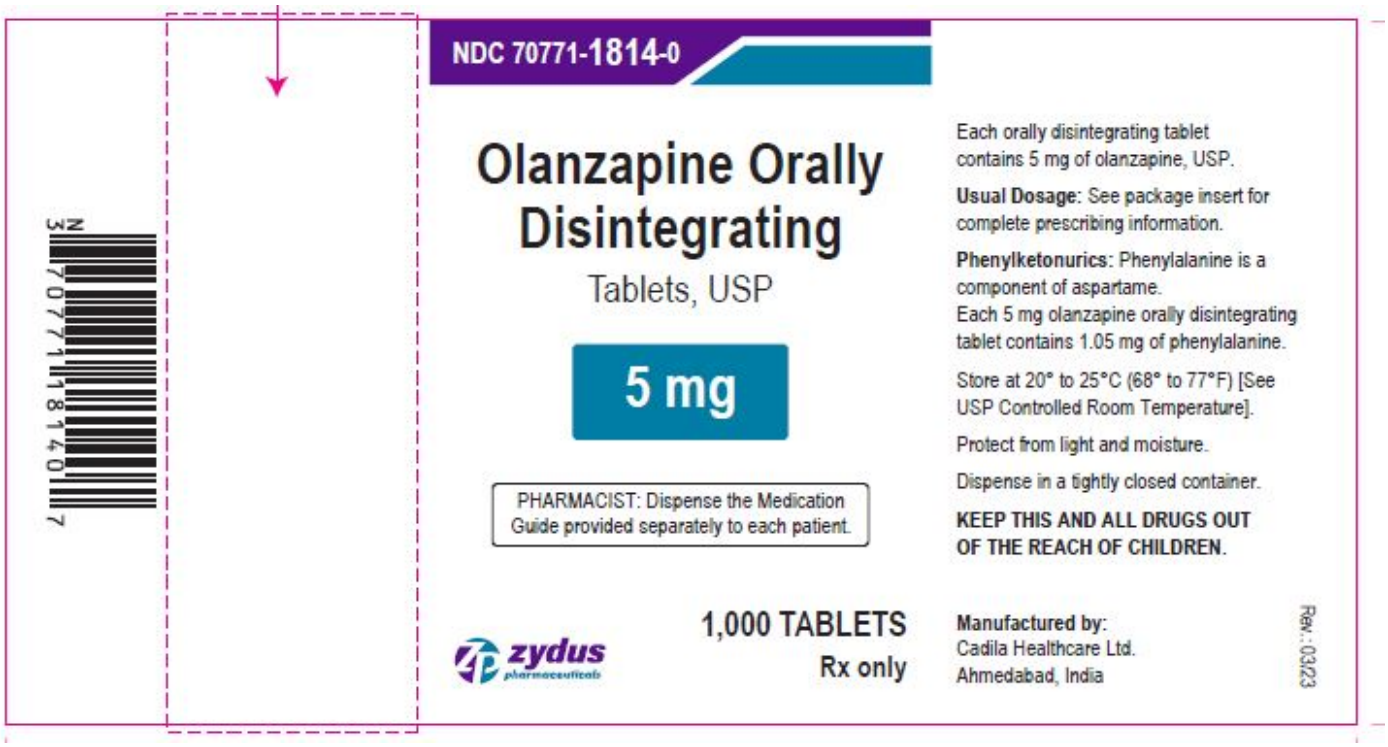
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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 70771-1816-0

Olanzapine Orally Disintegrating Tablets USP, 15 mg

Rx only

1,000 tablets

NDC 70771-1817-0

Olanzapine Orally Disintegrating Tablets USP, 20 mg

Rx only

1,000 tablets

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)	
CROSPOVIDONE (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

ASPARTAME (UNII: Z0H242BBR1)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSPOVIDONE (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)	
CROSPOVIDONE (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)	
CROSPOVIDONE (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

Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1814, 70771-1815, 70771-1816, 70771-1817) , MANUFACTURE(70771-1814, 70771-1815, 70771-1816, 70771-1817)