

ZOLMITRIPTAN- zolmitriptan tablet, orally disintegrating
Zydus Lifesciences Limited

ZOLMITRIPTAN ORALLY DISTRAGING TABLETS

NDC 65841-767-69 in blister pack of 6 Tablets

Zolmitriptan Orally Disintegrating Tablets, 2.5 mg

Rx only

6 Tablets



NDC 65841-768-87 in blister pack of 3 Tablets

Zolmitriptan Orally Disintegrating Tablets, 5 mg

Rx only

3 Tablets



Over Coding Template

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

NDC 65841-768-06

Zolmitriptan Orally Disintegrating Tablets, USP

5 mg

717

PHARMACIST: Dispense the Patient Information provided separately to each patient.

zydus pharmaceuticals

30 Tablets
Rx only

Each orally disintegrating tablet contains 5 mg of Zolmitriptan, USP.
Usual Dosage: See package insert for complete prescribing information.
Phenylketonurics: Contains Phenylalanine 5.01 mg Per Tablet.
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
 Protect from light and moisture.
 Dispense in a tight light-resistant closed container.
KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.
 Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India

Rev:1218

100 mm

28 mm

ZOLMITRIPTAN

zolmitriptan tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-767
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZOLMITRIPTAN (UNII: 2FS66TH3YW) (ZOLMITRIPTAN - UNII:2FS66TH3YW)	ZOLMITRIPTAN	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASPARTAME (UNII: Z0H242BBR1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ORANGE (UNII: 5EVU04N5QU)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	

Product Characteristics				
Color	WHITE (WHITE/MOTTLED WHITE TO CREAM WHITE)	Score	no score	
Shape	ROUND (ROUND)	Size	6mm	
Flavor	ORANGE (ORANGE)	Imprint Code	715	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-767-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
2	NDC:65841-767-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
3	NDC:65841-767-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
4	NDC:65841-767-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
5	NDC:65841-767-86	1 in 1 CARTON	05/16/2013	
5	NDC:65841-767-69	6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:65841-767-77	10 in 1 CARTON	05/16/2013	
6	NDC:65841-767-30	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	ANDA202890	05/16/2013		

ZOLMITRIPTAN			
zolmitriptan tablet, orally disintegrating			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-768
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	ZOLMITRIPTAN (UNII: 2FS66TH3YW) (ZOLMITRIPTAN - UNII:2FS66TH3YW)	ZOLMITRIPTAN	5 mg
Inactive Ingredients			
	Ingredient Name		Strength

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
ASPARTAME (UNII: Z0H242BBR1)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CROSPROVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)
GELATIN (UNII: 2G86QN327L)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MANNITOL (UNII: 3OWL53L36A)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
ORANGE (UNII: 5EVU04N5QU)
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)

Product Characteristics

Color	WHITE (WHITE/MOTTLED WHITE TO CREAM WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	9mm
Flavor	ORANGE (ORANGE)	Imprint Code	717
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-768-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
2	NDC:65841-768-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
3	NDC:65841-768-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
4	NDC:65841-768-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2013	
5	NDC:65841-768-82	1 in 1 CARTON	05/16/2013	
5	NDC:65841-768-87	3 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:65841-768-77	10 in 1 CARTON	05/16/2013	
6	NDC:65841-768-30	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	ANDA202890	05/16/2013	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-767, 65841-768) , MANUFACTURE(65841-767, 65841-768)

Revised: 8/2024

Zydus Lifesciences Limited