ZOLMITRIPTAN - zolmitriptan tablet, orally disintegrating
Zydus Lifesciences Limited

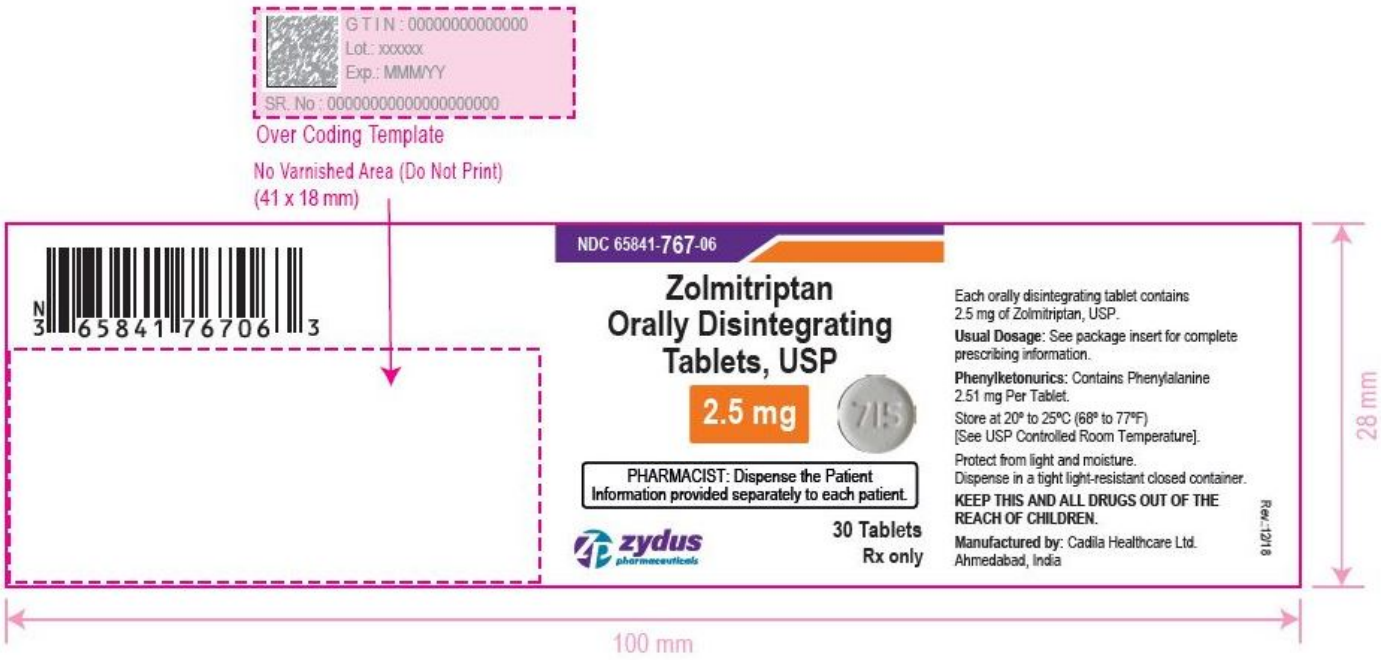
ZOLMITRIPTAN ORALLY DISTRAGING TABLETS

NDC 65841-767-10 in bottle of 1000 Tablets

Zolmitriptan Orally Disintegrating Tablets, 2.5 mg

Rx only

1000 Tablets

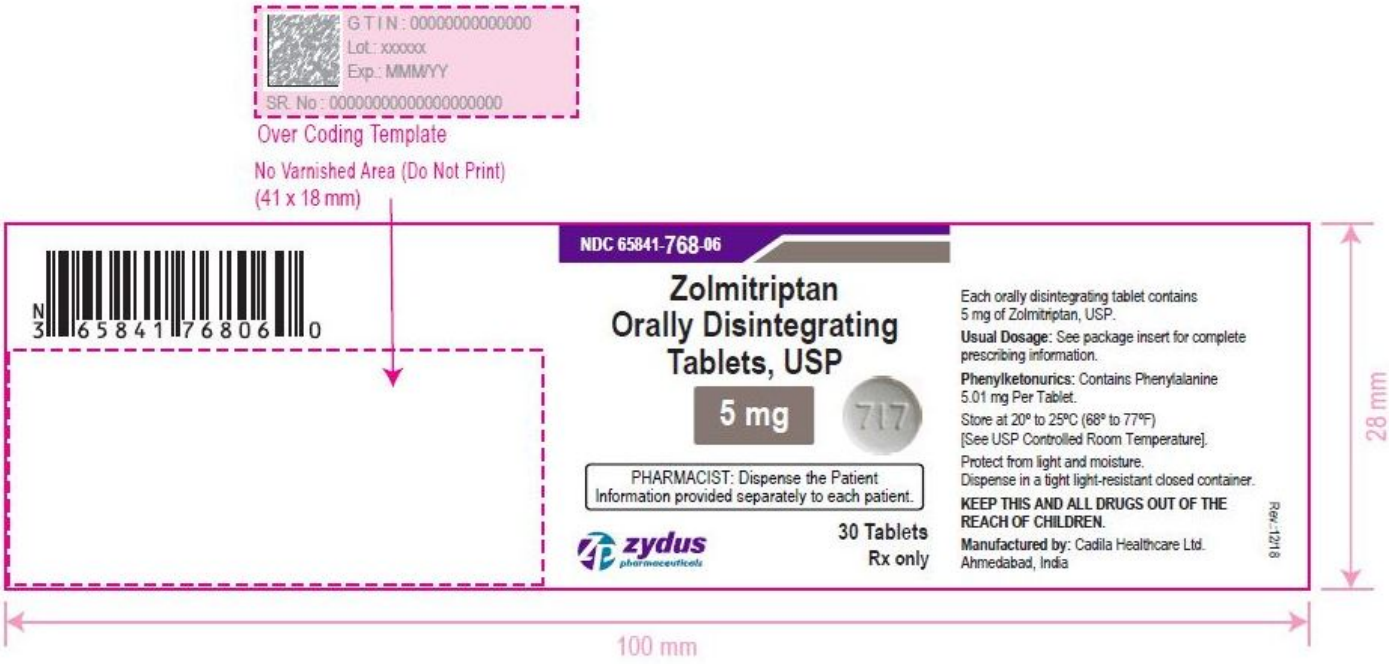


NDC 65841-768-10 in bottle of 1000 Tablets

Zolmitriptan Orally Disintegrating Tablets, 5 mg

Rx only

1000 Tablets



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)	
CROSPOVIDONE (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)	
CROSPOVIDONE (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)