

**ZOLMITRIPTAN - zolmitriptan tablet, film coated**  
**Zydus Lifesciences Limited**

**ZOLMITRIPTAN TABLETS**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-765-86 in unit-dose blister cartons of 6 (1 x 6) unit dose tablets

Zolmitriptan Tablets, 2.5 mg

Rx only

100 tablets

ZYDUS



## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-766-82 in unit-dose blister cartons of 3 (1 x 3) unit dose tablets

Zolmitriptan Tablets, 5 mg

Rx only

100 tablets

ZYDUS



## ZOLMITRIPTAN

zolmitriptan tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-765
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ZOLMITRIPTAN</b> (UNII: 2FS66TH3YW) (ZOLMITRIPTAN - UNII:2FS66TH3YW)	ZOLMITRIPTAN	2.5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS LACTOSE</b> (UNII: 3SY5LH9PMK)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLACRILIN POTASSIUM</b> (UNII: 0BZ5A00FQU)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	

## Product Characteristics

<b>Color</b>	YELLOW (LIGHT YELLOW to YELLOW)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	7
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:65841-765-86	1 in 1 CARTON	11/12/2018	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA203019	11/12/2018	

# ZOLMITRIPTAN

zolmitriptan tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-766
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ZOLMITRIPTAN (UNII: 2FS66TH3YW) (ZOLMITRIPTAN - UNII:2FS66TH3YW)	ZOLMITRIPTAN	5 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLACRILIN POTASSIUM (UNII: 0BZ5A00FQU)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	ORANGE (LIGHT ORANGE TO ORANGE)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	8mm
<b>Flavor</b>		<b>Imprint Code</b>	714
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-766-82	1 in 1 CARTON	11/12/2018	
1		3 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA203019	11/12/2018	

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

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Zydus Lifesciences Limited