

**ZONISAMIDE- zonisamide capsule**  
**Cadila Healthcare Limited**

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**Zonisamide Capsules**

**Manufactured by:**

Cadila Healthcare Ltd.  
India

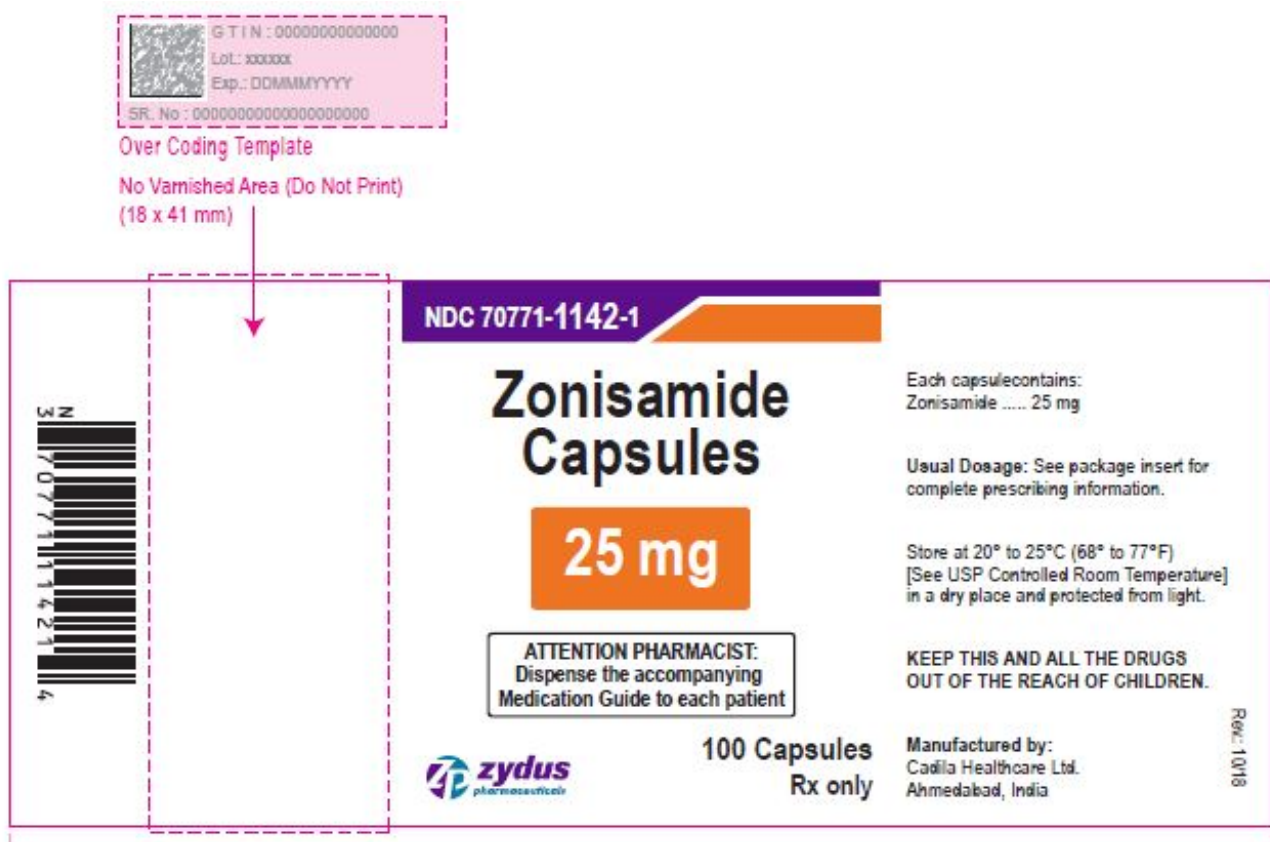
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1142-1 in bottle of 100 Capsules

Zonisamide Capsules, 25 mg

R<sub>x</sub> only

100 Capsules



NDC 70771-1143-1 in bottle of 100 Capsules

Zonisamide Capsules, 50 mg

R<sub>x</sub> only

100 Capsules

GTIN : 00000000000000  
Lot: xxxxxx  
Exp: DDMMYYYY  
SR. No : 000000000000000000

Over Coding Template

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

**NDC 70771-1143-1**

**Zonisamide Capsules**

**50 mg**

**100 Capsules**  
**Rx only**

Each capsule contains:  
Zonisamide ..... 50 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature]  
in a dry place and protected from light.

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

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 10/18

**ATTENTION PHARMACIST:**  
Dispense the accompanying  
Medication Guide to each patient

**zydus**  
pharmaceuticals

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3

NDC 70771-1144-1 in bottle of 100 Capsules

Zonisamide Capsules, 100 mg

R<sub>x</sub> only

100 Capsules

GTIN : 00000000000000  
 Lot: xxxxxx  
 Exp: DDMMYYYY  
 SR. No : 00000000000000000000

Over Coding Template  
 No Varnished Area (Do Not Print)  
 (18 x 50.5 mm)



**NDC 70771-1144-1**

# Zonisamide Capsules

**100 mg**

**ATTENTION PHARMACIST:**  
 Dispense the accompanying Medication Guide to each patient



**100 Capsules**  
Rx only

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Each capsule contains:  
Zonisamide ..... 100 mg

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature]  
in a dry place and protected from light.

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

Rev: 10/18

ZONISAMIDE			
zonisamide capsule			
Product Information			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70 771-1142
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ZONISAMIDE (UNII: 459384H98V) (ZONISAMIDE - UNII:459384H98V)	ZONISAMIDE	25 mg
Inactive Ingredients			
	<b>Ingredient Name</b>		<b>Strength</b>
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
	FD&C RED NO. 4 (UNII: X3W0AM1JLX)		
	GELATIN (UNII: 2G86QN327L)		
	HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)		
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

## Product Characteristics

<b>Color</b>	PINK (PINK) , WHITE (WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	14mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;31
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1142-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	
2	NDC:70771-1142-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077625	11/22/2017	

## ZONISAMIDE

zonisamide capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1143
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZONISAMIDE (UNII: 459384H98V) (ZONISAMIDE - UNII:459384H98V)	ZONISAMIDE	50 mg

### Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
GELATIN (UNII: 2G86QN327L)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	PINK (PINK) , WHITE (WHITE)	<b>Score</b>	no score
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<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	16 mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;32
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1143-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	
2	NDC:70771-1143-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077625	11/22/2017	

## ZONISAMIDE

zonisamide capsule

<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1144
<b>Route of Administration</b>	ORAL		

<b>Active Ingredient/Active Moiety</b>			
	Ingredient Name	Basis of Strength	Strength
	ZONISAMIDE (UNII: 459384H98V) (ZONISAMIDE - UNII:459384H98V)	ZONISAMIDE	100 mg

<b>Inactive Ingredients</b>		
	Ingredient Name	Strength
	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
	FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
	GELATIN (UNII: 2G86QN327L)	
	HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
	SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

<b>Product Characteristics</b>			
<b>Color</b>	PINK (PINK) , WHITE (WHITE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	19 mm
<b>Flavor</b>		<b>Imprint Code</b>	ZA;33
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1144-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	
2	NDC:70771-1144-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	
3	NDC:70771-1144-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/22/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077625	11/22/2017	

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

## Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(70771-1142, 70771-1143, 70771-1144) , MANUFACTURE(70771-1142, 70771-1143, 70771-1144)

Revised: 8/2020

Cadila Healthcare Limited