

ZONISAMIDE- zonisamide capsule
Zydus Lifesciences Limited

Zonisamide Capsules

Manufactured by:

Cadila Healthcare Ltd.

India

SPL MEDGUIDE

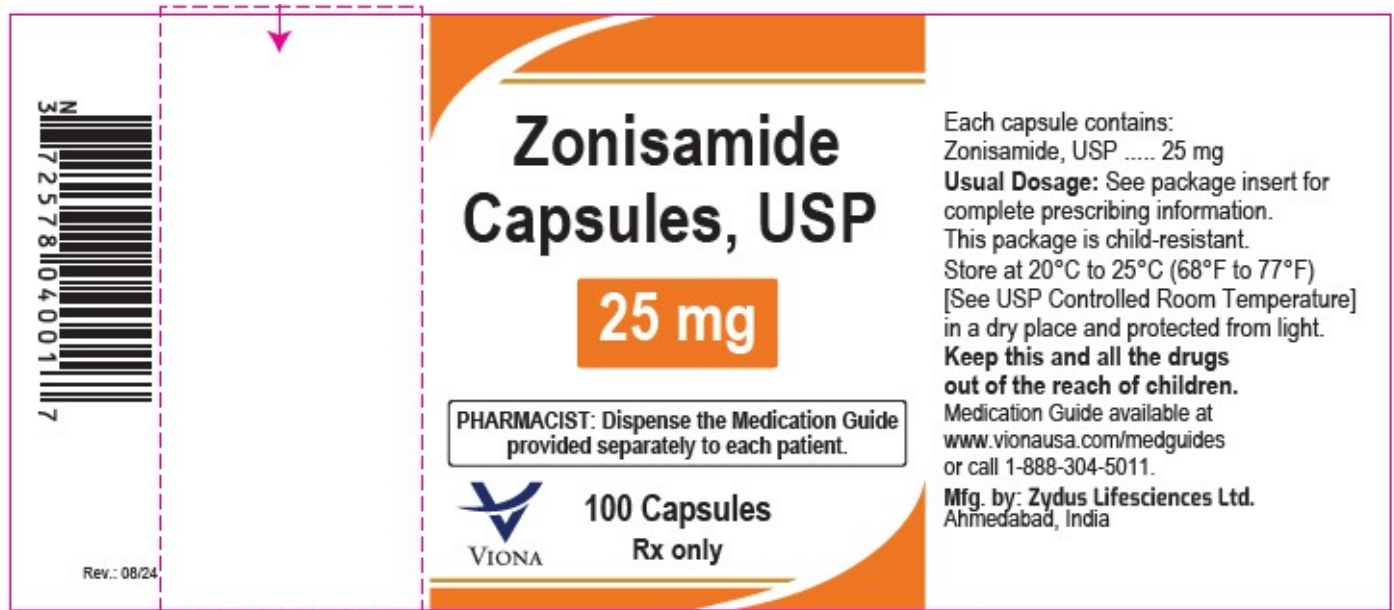
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1142-1 in bottle of 100 Capsules

Zonisamide Capsules, 25 mg

R_x only

100 Capsules



NDC 70771-1143-1 in bottle of 100 Capsules

Zonisamide Capsules, 50 mg

R_x only

100 Capsules

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4

Rev.: 08/24

Zonisamide Capsules, USP

50 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

VIONA 100 Capsules
Rx only

Each capsule contains:
Zonisamide, USP 50 mg
Usual Dosage: See package insert for complete prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F 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.
Medication Guide available at www.vionausa.com/medguides or call 1-888-304-5011.
Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India

NDC 70771-1144-1 in bottle of 100 Capsules

Zonisamide Capsules, 100 mg

R_x only

100 Capsules

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Rev.: 08/24

Zonisamide Capsules, USP

100 mg

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

VIONA 100 Capsules
Rx only

Each capsule contains:
Zonisamide, USP 100 mg
Usual Dosage: See package insert for complete prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F 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.
Medication Guide available at www.vionausa.com/medguides or call 1-888-304-5011.
Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India

ZONISAMIDE

zonisamide capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1142
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZONISAMIDE (UNII: 459384H98V) (ZONISAMIDE - UNII:459384H98V)	ZONISAMIDE	25 mg

Inactive Ingredients

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)	

Product Characteristics

Color	PINK (PINK) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	14mm
Flavor		Imprint Code	ZA;31;25;mg
Contains			

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

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1143
Route of Administration	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: 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

Color	PINK (PINK) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	16mm
Flavor		Imprint Code	ZA;32;50;mg
Contains			

Packaging

#	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	

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

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1144
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZONISAMIDE (UNII: 459384H98V) (ZONISAMIDE - UNII:459384H98V)	ZONISAMIDE	100 mg

Inactive Ingredients

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)	

Product Characteristics

Color	PINK (PINK) , WHITE (WHITE)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	19mm
Flavor		Imprint Code	ZA;33;100;mg
Contains			

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 - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

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

Revised: 8/2024

Zydus Lifesciences Limited