ZONISAMIDE- zonisamide capsule
Zydus Lifesciences Limited

Zonisamide Capsules

SPL MEDGUIDE

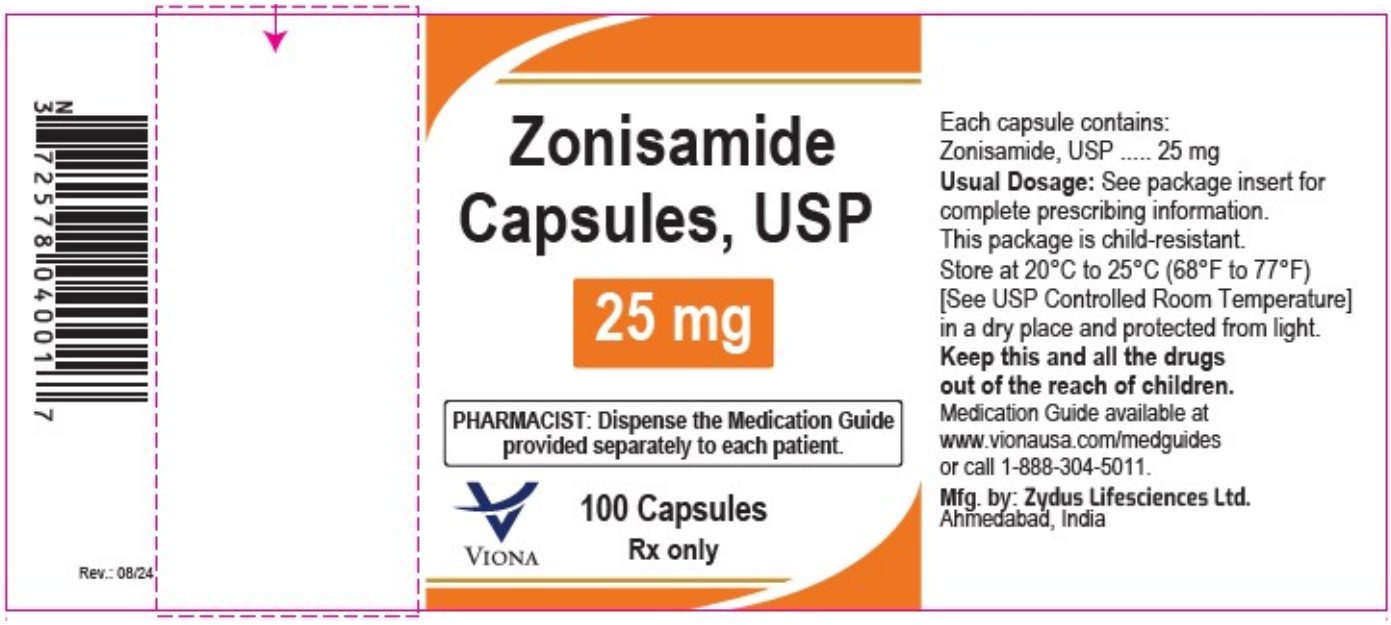
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1142-1 in bottle of 100 Capsules

Zonisamide Capsules, 25 mg

R_x only

100 Capsules

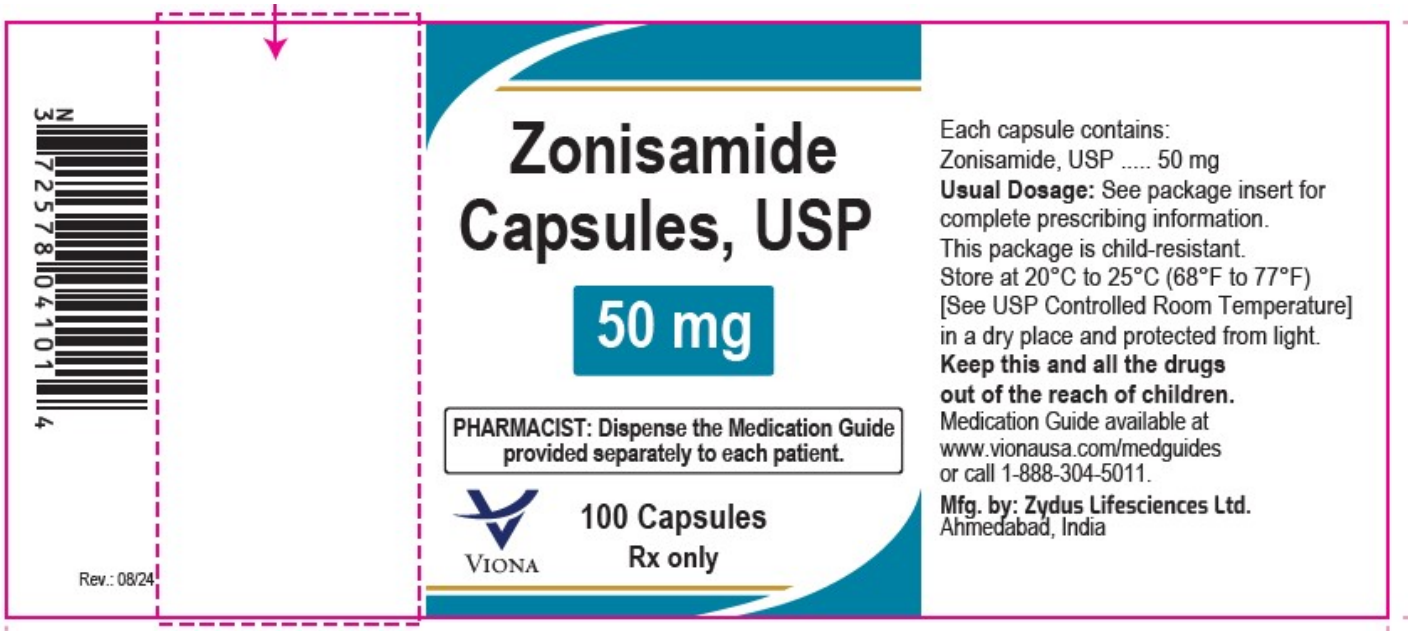


NDC 70771-1143-1 in bottle of 100 Capsules

Zonisamide Capsules, 50 mg

R_x only

100 Capsules

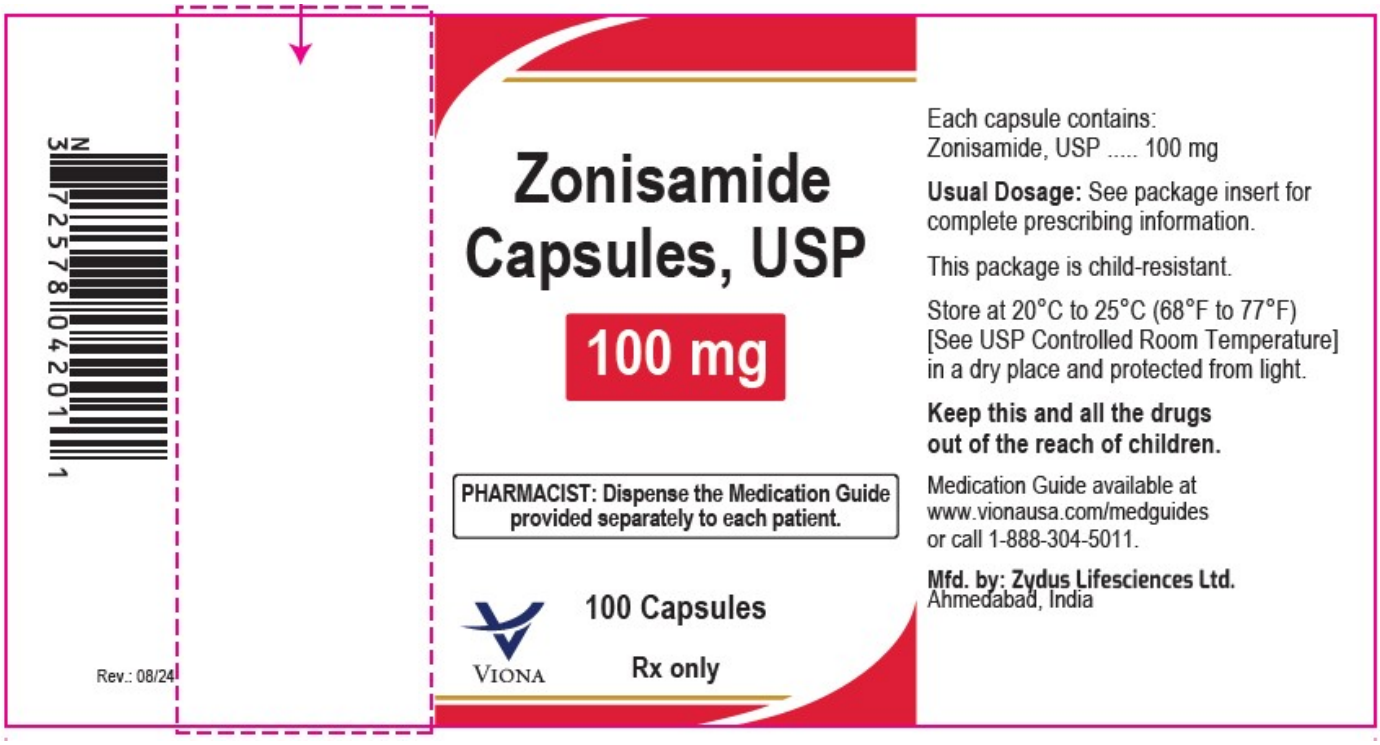


NDC 70771-1144-1 in bottle of 100 Capsules

Zonisamide Capsules, 100 mg

R_x only

100 Capsules



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. 40 (UNII: WZB9127XOA)	
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. 40 (UNII: WZB9127XOA)	
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

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. 40 (UNII: WZB9127XOA)	
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)