TOPIRAMATE- topiramate capsule, coated pellets
Zydus Lifesciences Limited

TOPIRAMATE TABLETS and TOPIRAMATE CAPSULES

SPL MEDGUIDE

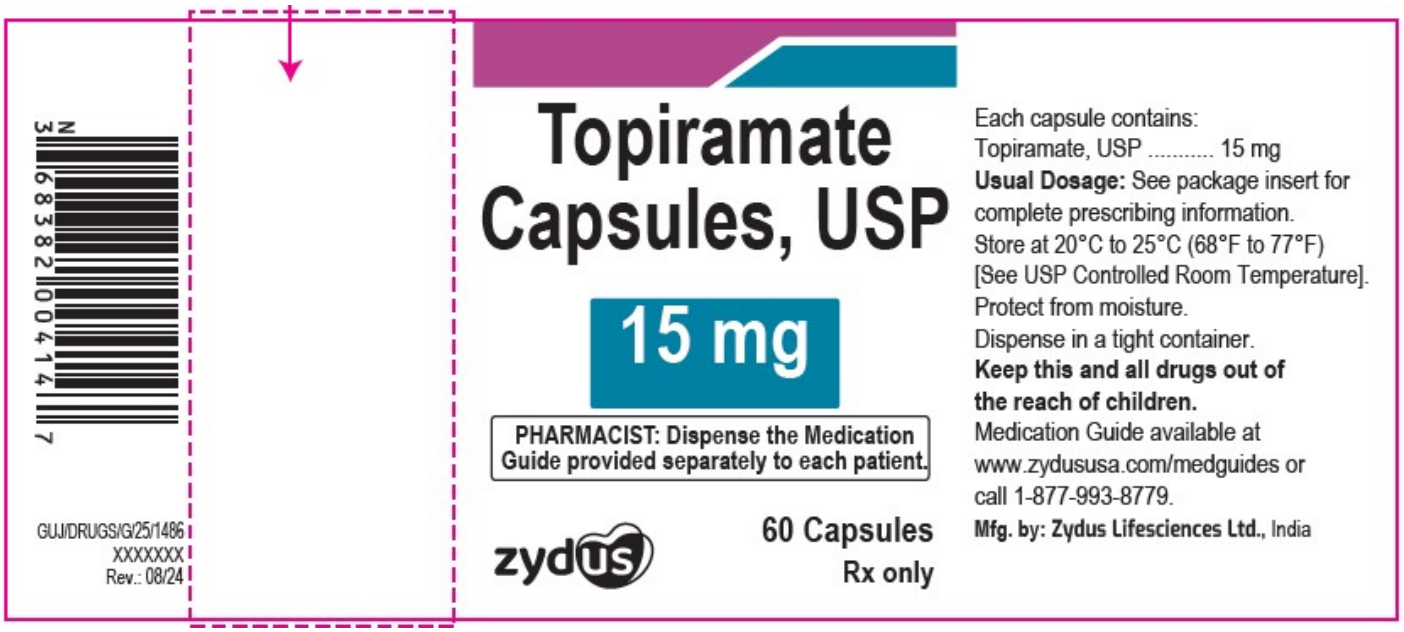
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-651-14 in bottle of 60 capsules

Topiramate Capsules USP, 15 mg

60 capsules

Rx only

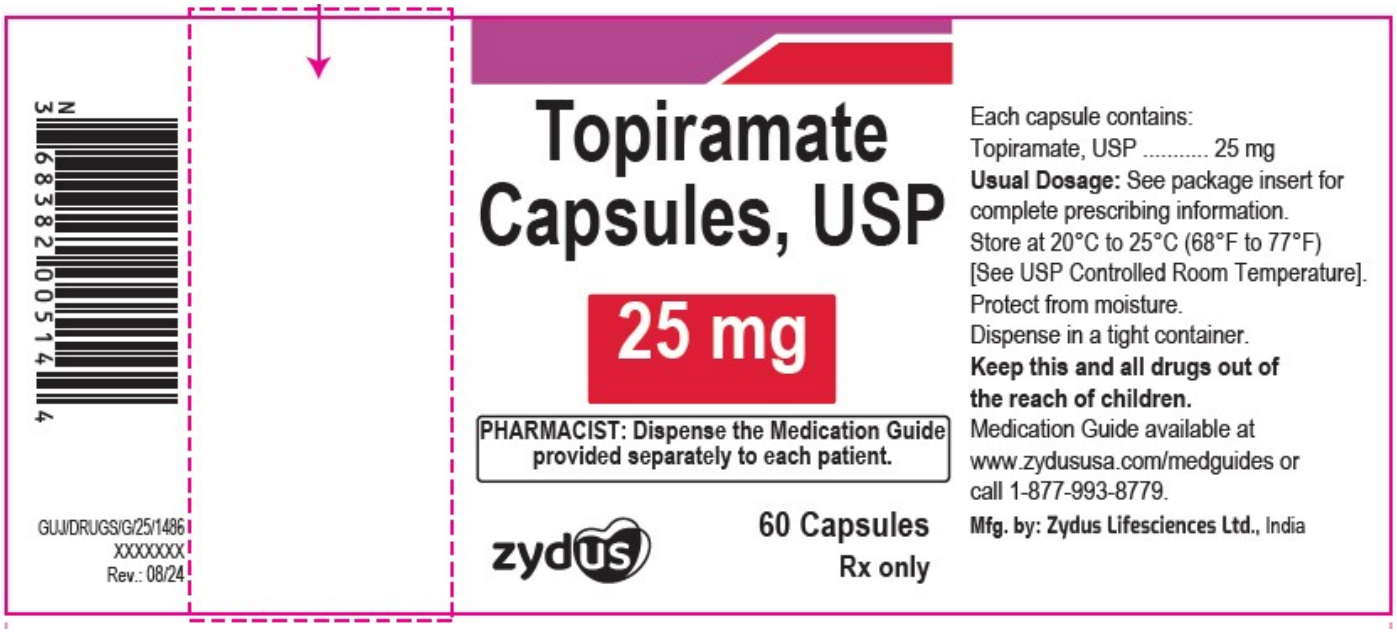


NDC 65841-652-14 in bottle of 60 capsules

Topiramate Capsules USP, 25 mg

60 capsules

Rx only

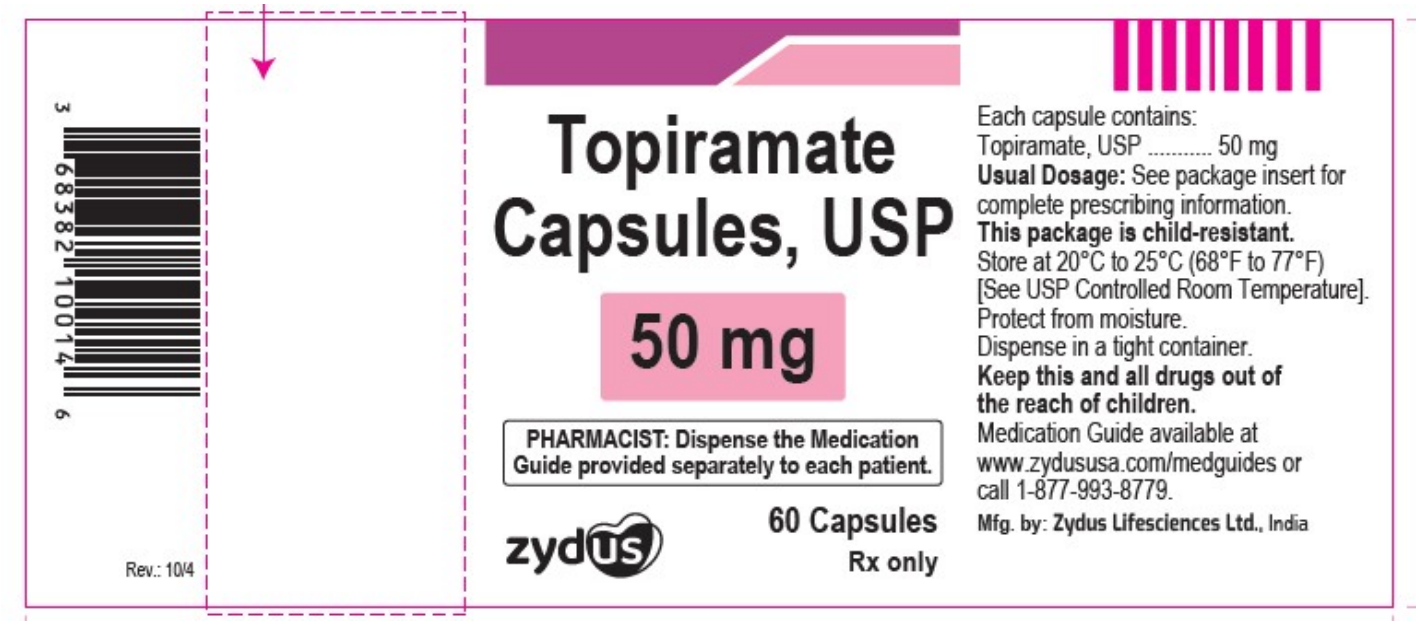


NDC 65841-100-14 in bottle of 60 capsules

Topiramate Capsules USP, 50 mg

60 capsules

Rx only



TOPIRAMATE

topiramate capsule, coated pellets

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-651
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	15 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	ZA63;15mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-651-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
2	NDC:65841-651-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
3	NDC:65841-651-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
4	NDC:65841-651-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
5	NDC:65841-651-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078877	10/14/2009	

TOPIRAMATE

topiramate capsule, coated pellets

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-652
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SHELLAC (UNII: 46N107B71O)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	ZA64;25mg
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-652-17	28 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
2	NDC:65841-652-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
3	NDC:65841-652-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	

4	NDC:65841-652-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
5	NDC:65841-652-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	
6	NDC:65841-652-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/14/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078877	10/14/2009	

TOPIRAMATE

topiramate capsule, coated pellets

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-846
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	50 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	22mm
Flavor		**Imprint Code**	50mg

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-846-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	10/24/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078877	10/24/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-651, 65841-652, 65841-846) , MANUFACTURE(65841-651, 65841-652, 65841-846)

Revised: 10/2024 Zydus Lifesciences Limited