

TOPIRAMATE- topiramate capsule, coated pellets
Zydus Lifesciences Limited

TOPIRAMATE TABLETS and TOPIRAMATE CAPSULES

SPL MEDGUIDE

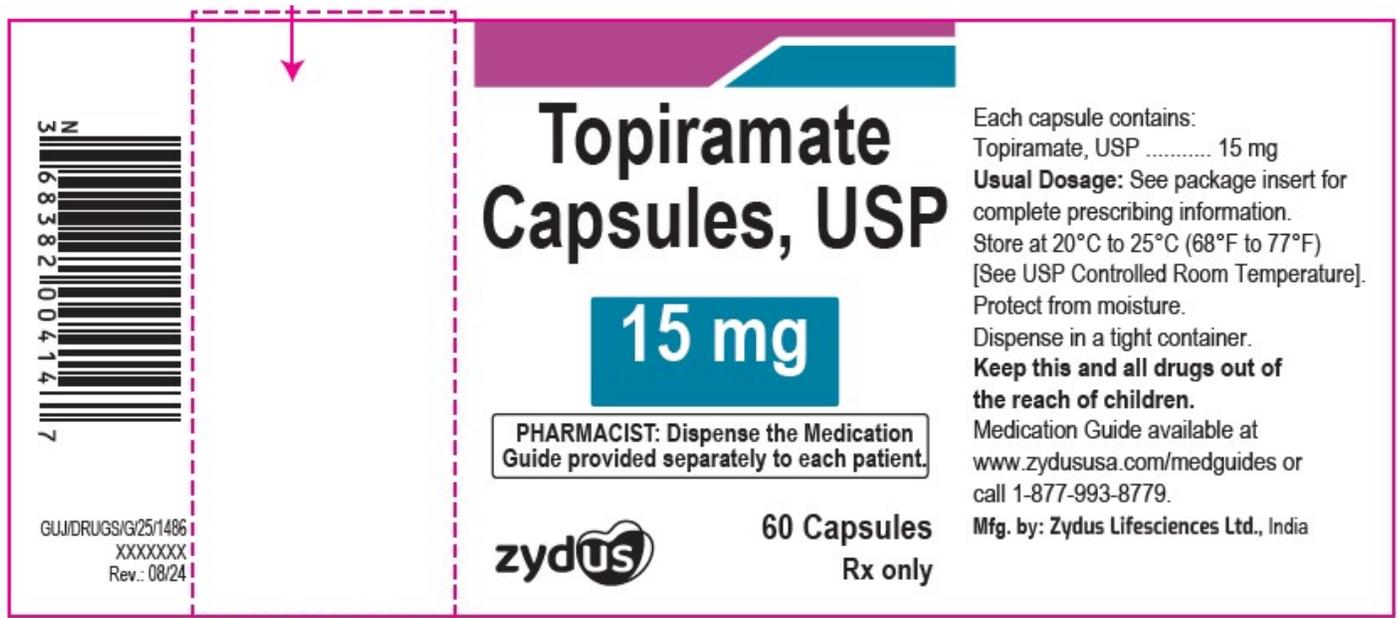
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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

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GUJ/DRUGS/G/25/1486
XXXXXXX
Rev.: 08/24

Topiramate Capsules, USP

25 mg

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

zydUS

60 Capsules
Rx only

Each capsule contains:
Topiramate, USP 25 mg
Usual Dosage: See package insert for complete prescribing information.
Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
Protect from moisture.
Dispense in a tight container.
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd., India

NDC 65841-100-14 in bottle of 60 capsules

Topiramate Capsules USP, 50 mg

60 capsules

Rx only

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Rev.: 10/4

Topiramate Capsules, USP

50 mg

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

zydUS

60 Capsules
Rx only

Each capsule contains:
Topiramate, 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].
Protect from moisture.
Dispense in a tight container.
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Mfg. by: Zydus Lifesciences Ltd., India

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: 0H73WJ391) (TOPIRAMATE - UNII:0H73WJ391)	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)	
FERROSFERRIC 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: 0H73WJ391) (TOPIRAMATE - UNII:0H73WJ391)	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)	
FERROSO FERRIC 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: 0H73WJ391) (TOPIRAMATE - UNII:0H73WJ391)	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)	
FERROSO FERRIC 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