

TOPIRAMATE - topiramate capsule, coated pellets
Zydus Lifesciences Limited

TOPIRAMATE TABLETS and TOPIRAMATE CAPSULES

SPL MEDGUIDE

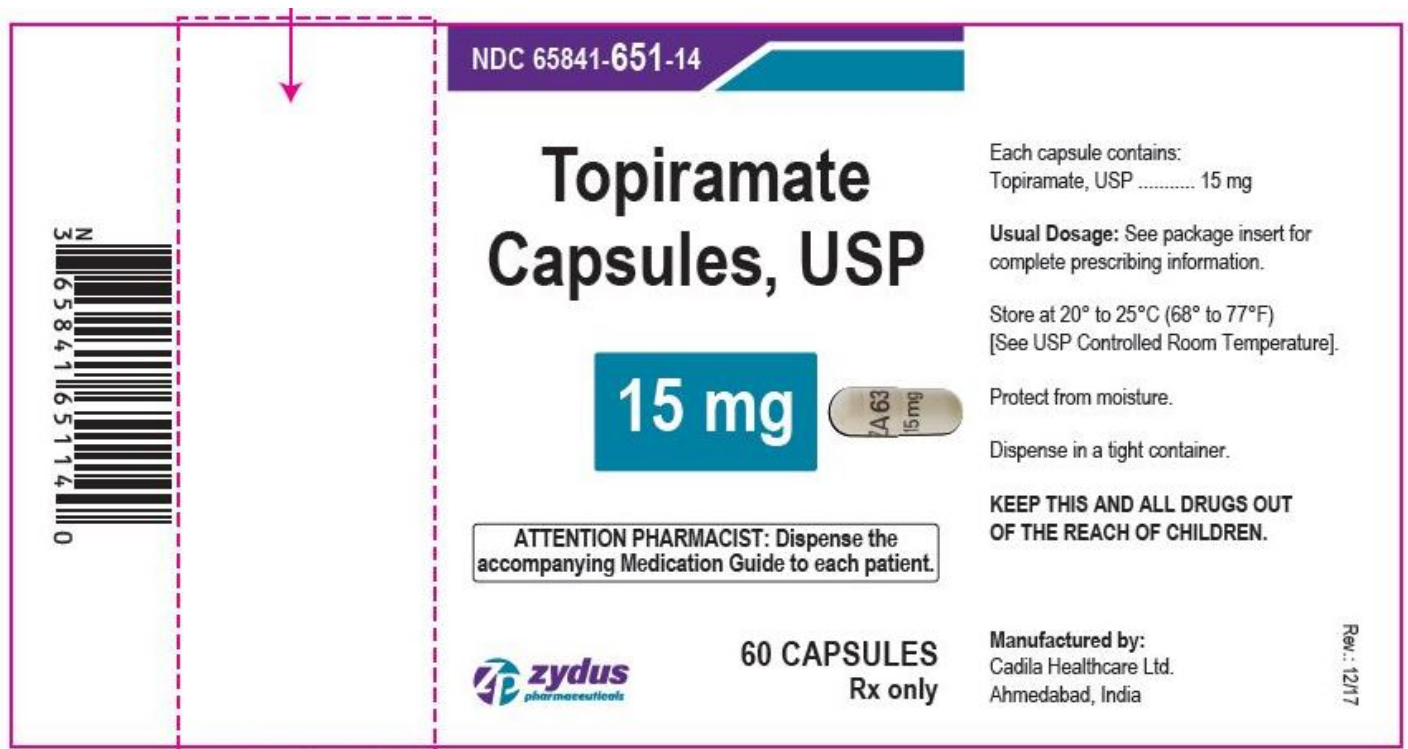
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

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 65841-652-14

Topiramate Capsules, USP



25 mg



60 CAPSULES
Rx only

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

Each capsule contains:
Topiramate, USP 25 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].
Protect from moisture.

Dispense in a tight container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev.: 12/17



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)	

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)	

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	

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) , MANUFACTURE(65841-651, 65841-652)

Revised: 10/2022

Zydus Lifesciences Limited