

TOPIRAMATE- topiramate tablet, film coated
Zydus Lifesciences Limited

TOPIRAMATE TABLETS and TOPIRAMATE CAPSULES

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-647-14 in bottle of 60 tablets

Topiramate Tablets USP, 25 mg

60 tablets

Rx only



NDC 65841-648-14 in bottle of 60 tablets

Topiramate Tablets USP, 50 mg

60 tablets

Rx only

NDC 65841-648-14

**Topiramate
Tablets, USP**

50 mg

Disperse the accompanying
Medication Guide to each patient

zydus
pharmaceuticals

60 TABLETS
Rx only

Each tablet contains:
Topiramate, USP 50 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.: 07/18

NDC 65841-649-14 in bottle of 60 tablets
 Topiramate Tablets USP, 100 mg
 60 tablets
 Rx only

NDC 65841-649-14

**Topiramate
Tablets, USP**

100 mg

Disperse the accompanying
Medication Guide to each patient

zydus
pharmaceuticals

60 TABLETS
Rx only

Each tablet contains:
Topiramate, USP 100 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.: 07/18

NDC 65841-650-14 in bottle of 60 tablets
 Topiramate Tablets USP, 200 mg
 60 tablets
 Rx only

NDC 65841-650-14

Topiramate Tablets, USP

200 mg

Dispense the accompanying Medication Guide to each patient

Each tablet contains:
Topiramate, USP 200 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.: 07/18

60 TABLETS
Rx only

TOPIRAMATE			
topiramate tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-647
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)			
MAGNESIUM STEARATE (UNII: 70097M6130)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			
Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	6mm

Flavor		Imprint Code	ZD;16	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-647-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
2	NDC:65841-647-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
3	NDC:65841-647-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
4	NDC:65841-647-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078235	03/27/2009		

TOPIRAMATE			
topiramate tablet, film coated			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-648
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)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)			

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	ZD;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-648-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
2	NDC:65841-648-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
3	NDC:65841-648-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
4	NDC:65841-648-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078235	03/27/2009	

TOPIRAMATE

topiramate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-649
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	100 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	ZD;14
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-649-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
2	NDC:65841-649-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
3	NDC:65841-649-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
4	NDC:65841-649-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078235	03/27/2009	

TOPIRAMATE

topiramate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-650
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	200 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	12mm
Flavor		Imprint Code	ZD;13
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-650-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
2	NDC:65841-650-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
3	NDC:65841-650-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	
4	NDC:65841-650-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2009	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078235	03/27/2009	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-647, 65841-648, 65841-649, 65841-650) , MANUFACTURE(65841-647, 65841-648, 65841-649, 65841-650)