

**TOPIRAMATE- topiramate tablet, film coated**  
**Cadila Healthcare Limited**

**TOPIRAMATE TABLETS and TOPIRAMATE CAPSULES**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 65841-647-14 in bottle of 60 tablets

Topiramate Tablets USP, 25 mg

60 tablets

Rx only

NDC 65841-647-14

**Topiramate  
Tablets, USP**

**25 mg**

Dispense the accompanying  
Medication Guide to each patient

**60 TABLETS**  
Rx only

Each tablet 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.: 07/18

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**

Dispense 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**

Dispense 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.

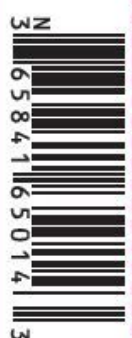
**KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.**

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.**

Rev.: 07/18



**60 TABLETS**  
Rx only

**Manufactured by:**  
Cadila Healthcare Ltd.  
Ahmedabad, India

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: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	25 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	6 mm
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: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	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** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

**Establishment**

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

Revised: 9/2020

Cadila Healthcare Limited