

**TOPIRAMATE- topiramate capsule, extended release**  
**Zydus Lifesciences Limited**

**TOPIRAMATE EXTENDED-RELEASE CAPSULES**

**SPL MEDGUIDE**

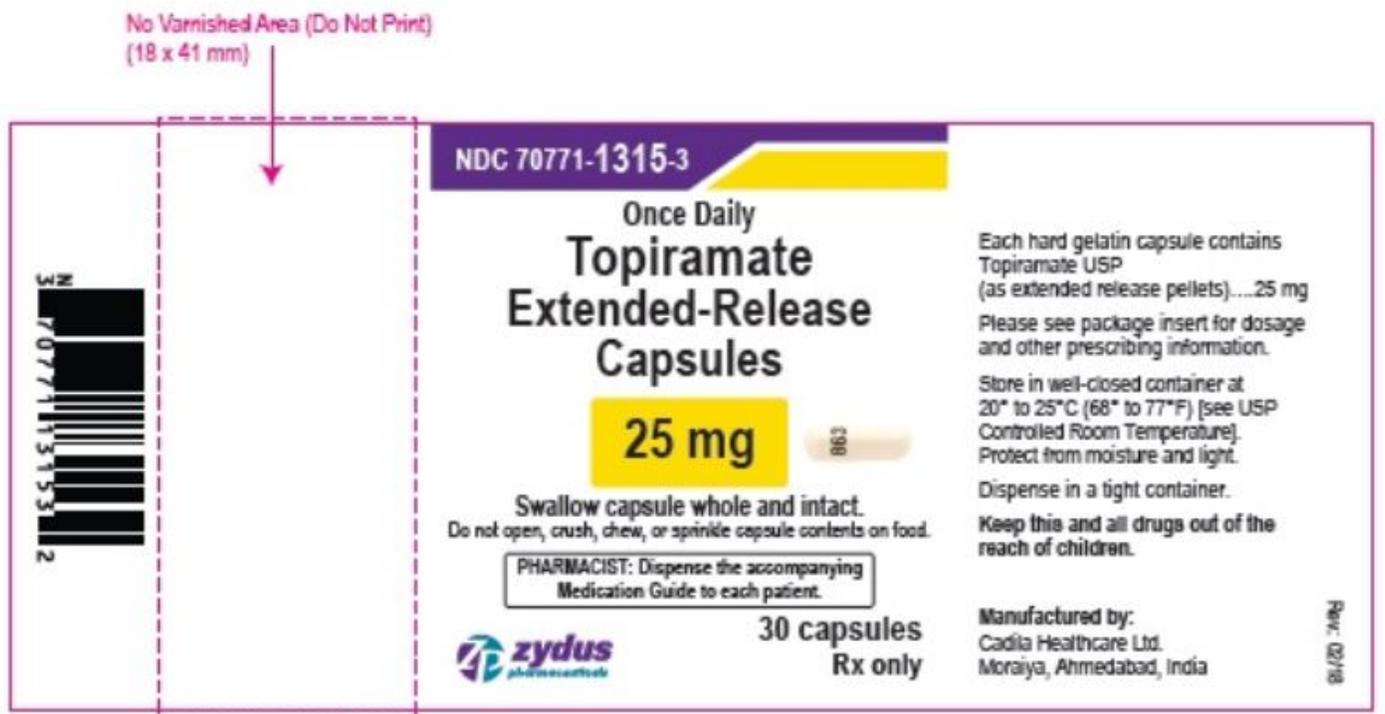
**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 70771-1315-3

Topiramate extended-release capsules, 25 mg

30 capsules

Rx only



NDC 70771-1316-3

Topiramate extended-release capsules, 50 mg

30 capsules

Rx only

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1316-3

Once Daily  
**Topiramate  
Extended-Release  
Capsules**

**50 mg**

Swallow capsule whole and intact.  
Do not open, crush, chew, or sprinkle capsule contents on food.

PHARMACIST: Dispense the accompanying  
Medication Guide to each patient.

**zydus**  
pharmaceuticals

30 capsules  
Rx only

Each hard gelatin capsule contains  
Topiramate USP  
(as extended release pellets)...50 mg

Please see package insert for dosage  
and other prescribing information.

Store in well-closed container at  
20° to 25°C (68° to 77°F) [see USP  
Controlled Room Temperature].  
Protect from moisture and light.

Dispense in a tight container.

Keep this and all drugs out of the  
reach of children.

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

Rev: 02/18

NDC 70771-1317-3

Topiramate extended-release capsules, 100 mg

30 capsules

Rx only

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1317-3

Once Daily  
**Topiramate  
Extended-Release  
Capsules**

**100 mg**

Swallow capsule whole and intact.  
Do not open, crush, chew, or sprinkle capsule contents on food.

PHARMACIST: Dispense the accompanying  
Medication Guide to each patient.

**zydus**  
pharmaceuticals

30 capsules  
Rx only

Each hard gelatin capsule contains  
Topiramate USP  
(as extended release pellets)...100 mg

Please see package insert for dosage  
and other prescribing information.

Store in well-closed container at  
20° to 25°C (68° to 77°F) [see USP  
Controlled Room Temperature].  
Protect from moisture and light.

Dispense in a tight container.

Keep this and all drugs out of the  
reach of children.

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

Rev: 02/18

NDC 70771-1858-3

Topiramate extended-release capsules, 200 mg

30 capsules

Rx only

Once Daily  
**Topiramate**  
**Extended-Release**  
**Capsules**  
**200 mg**

Swallow capsule whole and intact.  
Do not open, crush, chew,  
or sprinkle capsule contents on food.

PHARMACIST: Dispense the accompanying  
Medication Guide to each patient.

**zydus** 30 Capsules  
Rx only

Each hard gelatin capsule contains Topiramate USP (as extended release pellets)...200 mg. Please see package insert for dosage and other prescribing information. **This package is child-resistant.** Store in well-closed container at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from moisture and light. Dispense in a light container. **Keep this and all drugs out of the reach of children.** Medication Guide available at [www.zydususa.com/medguides](http://www.zydususa.com/medguides) or call 1-877-993-8779. Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India

Rev.: 11/23

## TOPIRAMATE

topiramate capsule, extended release

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1315
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POVIDONE (UNII: FZ989GH94E)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	863
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1315-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
2	NDC:70771-1315-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
3	NDC:70771-1315-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
4	NDC:70771-1315-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
5	NDC:70771-1315-4	10 in 1 CARTON	04/05/2018	
5	NDC:70771-1315-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207382	04/05/2018	

## TOPIRAMATE

topiramate capsule, extended release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1316
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>TOPIRAMATE</b> (UNII: 0H73WJ391) (TOPIRAMATE - UNII:0H73WJ391)	TOPIRAMATE	50 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>ETHYLCELLULOSE, UNSPECIFIED</b> (UNII: 7Z8S9VYZ4B)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	864
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1316-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
2	NDC:70771-1316-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
3	NDC:70771-1316-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
4	NDC:70771-1316-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
5	NDC:70771-1316-4	10 in 1 CARTON	04/05/2018	
5	NDC:70771-1316-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207382	04/05/2018	

# TOPIRAMATE

topiramate capsule, extended release

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1317
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TOPIRAMATE</b> (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	100 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>BUTYL ALCOHOL</b> (UNII: 8PJ61P6TS3)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>ETHYLCELLULOSE, UNSPECIFIED</b> (UNII: 7Z8S9VYZ4B)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	23mm
<b>Flavor</b>		<b>Imprint Code</b>	769
<b>Contains</b>			

## Packaging

Marketing Start      Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1317-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
2	NDC:70771-1317-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
3	NDC:70771-1317-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
4	NDC:70771-1317-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/05/2018	
5	NDC:70771-1317-4	10 in 1 CARTON	04/05/2018	
5	NDC:70771-1317-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207382	04/05/2018	

## TOPIRAMATE

topiramate capsule, extended release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1858
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TOPIRAMATE</b> (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>ETHYLCELLULOSE, UNSPECIFIED</b> (UNII: 7Z8S9VYZ4B)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE (90000 WAMW)</b> (UNII: UKE75GEA7F)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**TRIETHYL CITRATE** (UNII: 8Z96QXD6UM)

**WATER** (UNII: 059QF0KO0R)

### Product Characteristics

<b>Color</b>	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	24mm
<b>Flavor</b>		<b>Imprint Code</b>	358
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1858-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2023	
2	NDC:70771-1858-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2023	
3	NDC:70771-1858-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/13/2023	
4	NDC:70771-1858-8	3 in 1 CARTON	11/13/2023	
4	NDC:70771-1858-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207382	11/13/2023	

**Labeler** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1315, 70771-1316, 70771-1317, 70771-1858) , MANUFACTURE(70771-1315, 70771-1316, 70771-1317, 70771-1858)

Revised: 11/2023

Zydus Lifesciences Limited