

TOPIRAMATE- topiramate capsule, extended release
Zydus Lifesciences Limited

TOPIRAMATE extended-release capsules, for oral use

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1656-3

Topiramate extended-release Capsules 25 mg

Rx only

30 Capsules

NDC 70771-1656-3

**Topiramate
Extended-Release
Capsules**

25 mg

Once-Daily Dosing

PHARMACIST: Dispense the medication
guide provided separately to each patient.

zydus

**30 Capsules
Rx only**

Each capsule contains:
Topiramate, USP.....25 mg.

Recommended dosage: Administer dose
once daily. See Prescribing Information.

This package is child-resistant.

Store in a tightly 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.

**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.
Ahmedabad, India

Rev.: 12/22


NDC 70771-1657-3

Topiramate extended-release Capsules 50 mg

Rx only

30 Capsules

NDC 70771-1657-3



3
70771-1657-3
5

Rev.: 12/22

**Topiramate
Extended-Release
Capsules**

50 mg

Once-Daily Dosing

PHARMACIST: Dispense the medication
guide provided separately to each patient.

zydus

30 Capsules
Rx only

Each capsule contains:
Topiramate, USP.....50 mg.

Recommended dosage: Administer dose
once daily. See Prescribing Information.

This package is child-resistant.

Store in a tightly 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.

**Keep this and all drugs out of
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Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India


NDC 70771-1658-3

Topiramate extended-release Capsules 100 mg

Rx only

30 Capsules

NDC 70771-1658-3



3
70771-1658-3
4

Rev.: 12/22

**Topiramate
Extended-Release
Capsules**

100 mg

Once-Daily Dosing

PHARMACIST: Dispense the medication
guide provided separately to each patient.

zydus

30 Capsules
Rx only

Each capsule contains:
Topiramate, USP.....100 mg.

Recommended dosage: Administer dose
once daily. See Prescribing Information.

This package is child-resistant.

Store in a tightly 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.

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

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Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India

NDC 70771-1659-3

Topiramate extended-release Capsules 150 mg

Rx only

30 Capsules

NDC 70771-1659-3

**Topiramate
Extended-Release
Capsules**

150 mg

Once-Daily Dosing

PHARMACIST: Dispense the medication
guide provided separately to each patient.

zydus

30 Capsules
Rx only

Each capsule contains:
Topiramate, USP.....150 mg.

Recommended dosage: Administer dose
once daily. See Prescribing Information.

This package is child-resistant.

Store in a tightly 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.

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

Medication Guide available at
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call 1-877-993-8779.

Mfg. by: Zydus Lifesciences Ltd.
Ahmedabad, India

Rev.: 12/22

NDC 70771-1660-3

Topiramate extended-release Capsules 200 mg

Rx only

30 Capsules

NDC 70771-1660-3

**Topiramate
Extended-Release
Capsules**

200 mg

Once-Daily Dosing

PHARMACIST: Dispense the medication
guide provided separately to each patient.

zydus

30 Capsules
Rx only

Each capsule contains:
Topiramate, USP.....200 mg.

Recommended dosage: Administer dose
once daily. See Prescribing Information.

This package is child-resistant.

Store in a tightly 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.

**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.
Ahmedabad, India

Rev.: 12/22

TOPIRAMATE

topiramate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1656
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Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	25 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
ETHYLCELLULOSE (45 MPA.S) (UNII: V7AD894FAZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	PINK (FLESH OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	14mm
Flavor		Imprint Code	1039
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1656-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	
2	NDC:70771-1656-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208949	01/17/2023	

TOPIRAMATE

topiramate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1657
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
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
ETHYLCELLULOSE (45 MPA.S) (UNII: V7AD894FAZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (IVORY OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	18mm
Flavor		Imprint Code	1040
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1657-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	

2	NDC:70771-1657-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023
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Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208949	01/17/2023	

TOPIRAMATE

topiramate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1658
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJ391) (TOPIRAMATE - UNII:0H73WJ391)	TOPIRAMATE	100 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
ETHYLCELLULOSE (45 MPA.S) (UNII: V7AD894FAZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE (MEDIUM ORANGE OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	Score	no score
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Shape	CAPSULE (CAPSULE)			Size	19mm
Flavor				Imprint Code	1041
Contains					
Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70771-1658-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023		
2	NDC:70771-1658-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023		
Marketing Information					
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date	
ANDA	ANDA208949		01/17/2023		

TOPIRAMATE

topiramate capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1659
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TOPIRAMATE (UNII: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)		TOPIRAMATE	150 mg
Inactive Ingredients			
Ingredient Name			Strength
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)			
ETHYLCELLULOSE (45 MPA.S) (UNII: V7AD894FAZ)			
FERROSFERRIC OXIDE (UNII: XM0M87F357)			
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)			
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 36SFW2JZ0W)			
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SHELLAC (UNII: 46N107B71O)			
TALC (UNII: 7SEV7J4R1U)			

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color	WHITE (WHITE OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	22mm
Flavor		Imprint Code	1042
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1659-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	
2	NDC:70771-1659-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208949	01/17/2023	

TOPIRAMATE

topiramate capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1660
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
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
ETHYLCELLULOSE (45 MPA.S) (UNII: V7AD894FAZ)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
HYPROMELLOSE 2910 (15 MPA.S) (UNII: 365FW2JZ0W)	

HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KOOR)	

Product Characteristics			
Color	GREEN (LIGHT GREEN OPAQUE CAP) , WHITE (WHITE OPAQUE BODY)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	23mm
Flavor		Imprint Code	1043
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1660-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	
2	NDC:70771-1660-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/17/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208949	01/17/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment			
Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1656, 70771-1657, 70771-1658, 70771-1659, 70771-1660) , MANUFACTURE(70771-1656, 70771-1657, 70771-1658, 70771-1659, 70771-1660)