TOPIRAMATE- topiramate capsule, extended release
Zydus Lifesciences Limited

TOPIRAMATE extended-release capsules, for oral use

SPL MEDGUIDE

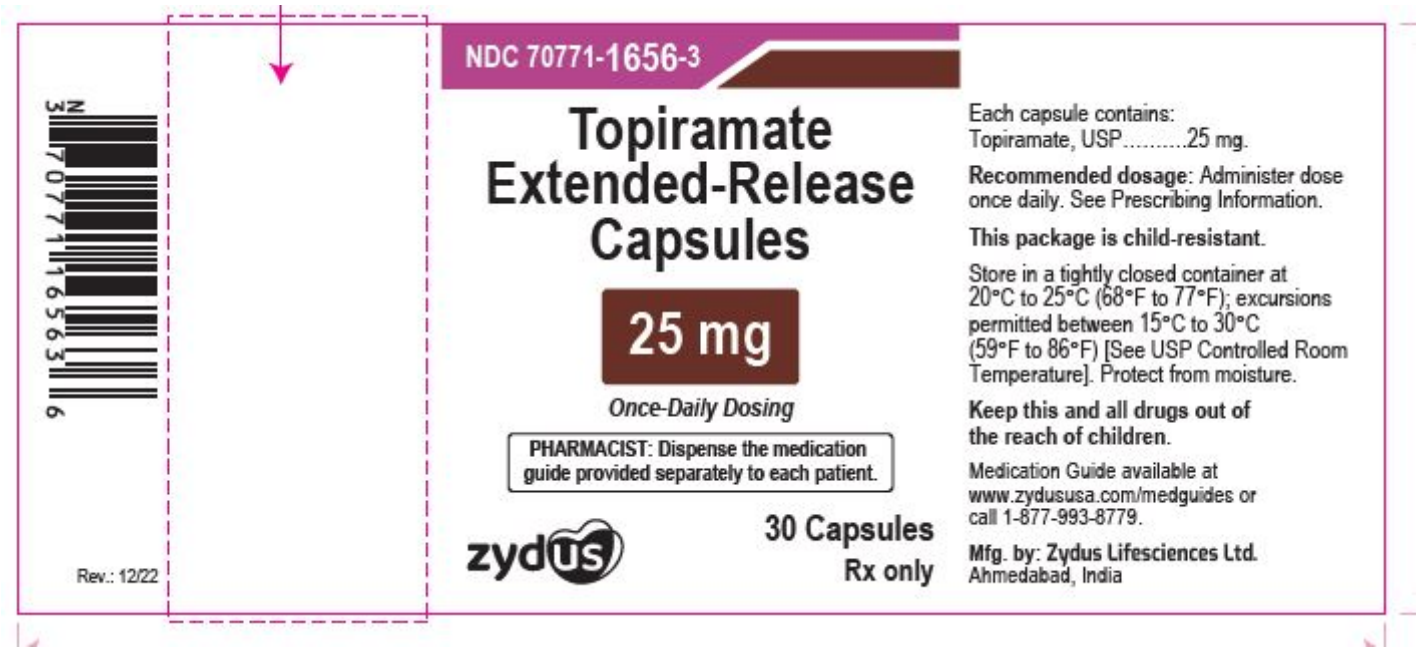
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1656-3

Topiramate extended-release Capsules 25 mg

Rx only

30 Capsules

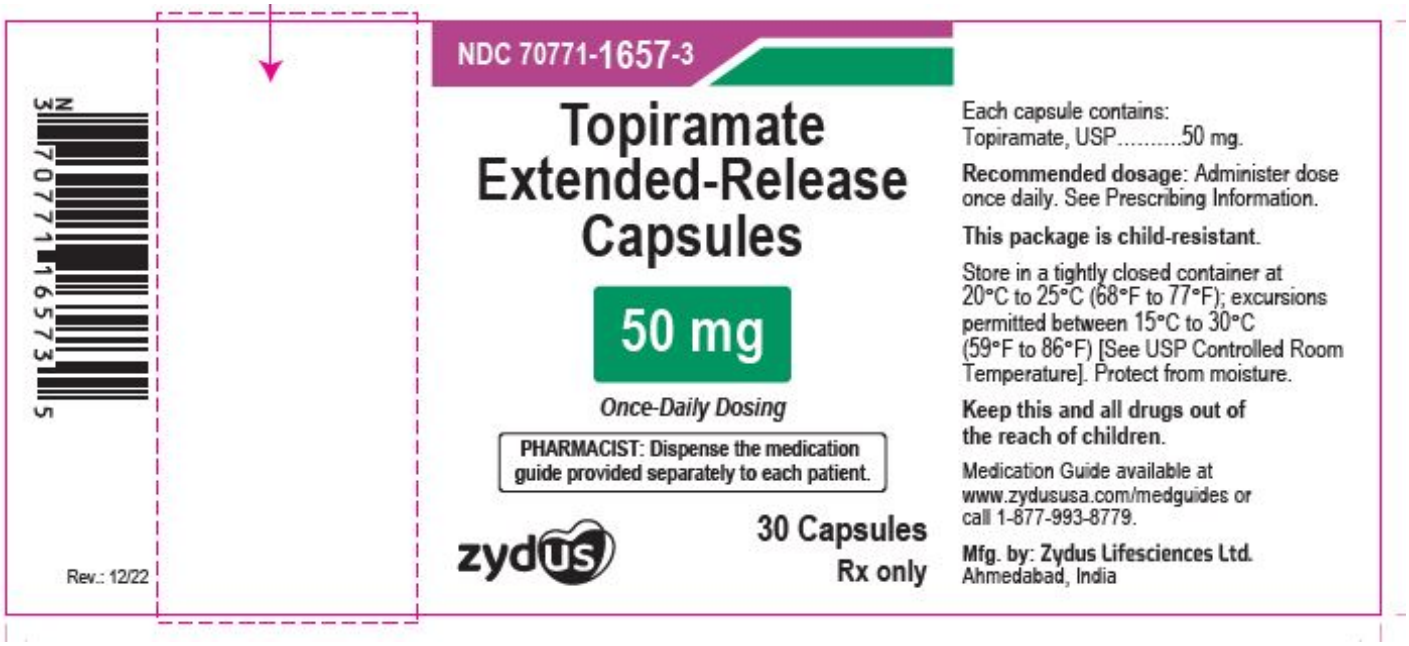


NDC 70771-1657-3

Topiramate extended-release Capsules 50 mg

Rx only

30 Capsules

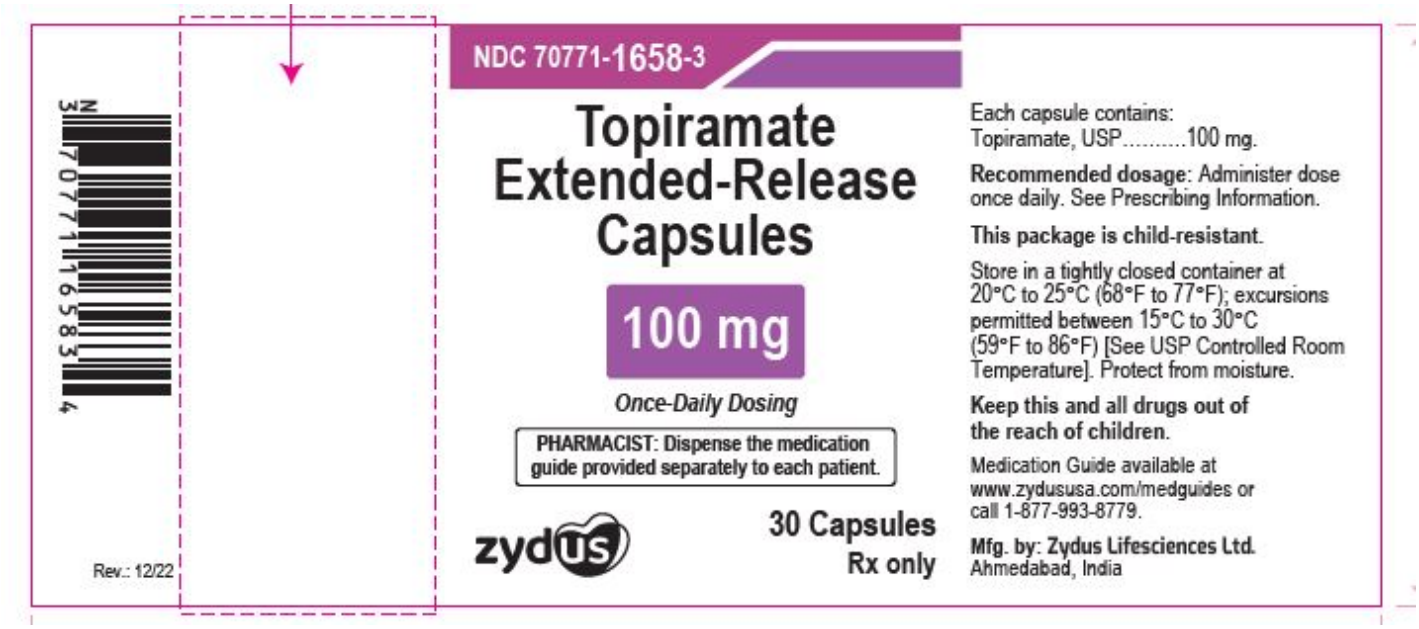


NDC 70771-1658-3

Topiramate extended-release Capsules 100 mg

Rx only

30 Capsules

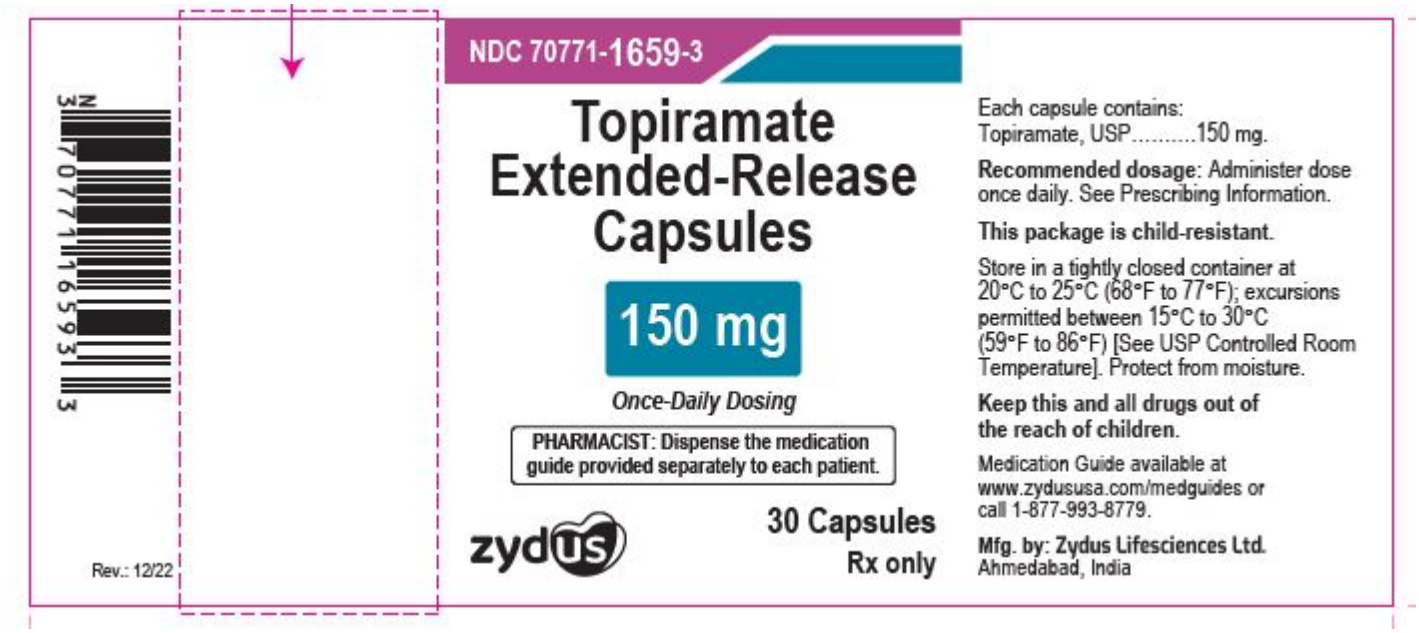


NDC 70771-1659-3

Topiramate extended-release Capsules 150 mg

Rx only

30 Capsules



NDC 70771-1660-3

Topiramate extended-release Capsules 200 mg

Rx only

30 Capsules

TOPIRAMATE

topiramate capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1656

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
ETHYLCELLULOSE (10 MPA.S) (UNII: 3DYK7UYZ62)	
ETHYLCELLULOSE (45 MPA.S) (UNII: V7AD894FAZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
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	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)	
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	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	

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: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	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

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)	
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	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)	
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	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)