TOPIRAMATE- topiramate capsule, extended release
Zydus Lifesciences Limited

TOPIRAMATE EXTENDED-RELEASE CAPSULES

SPL MEDGUIDE

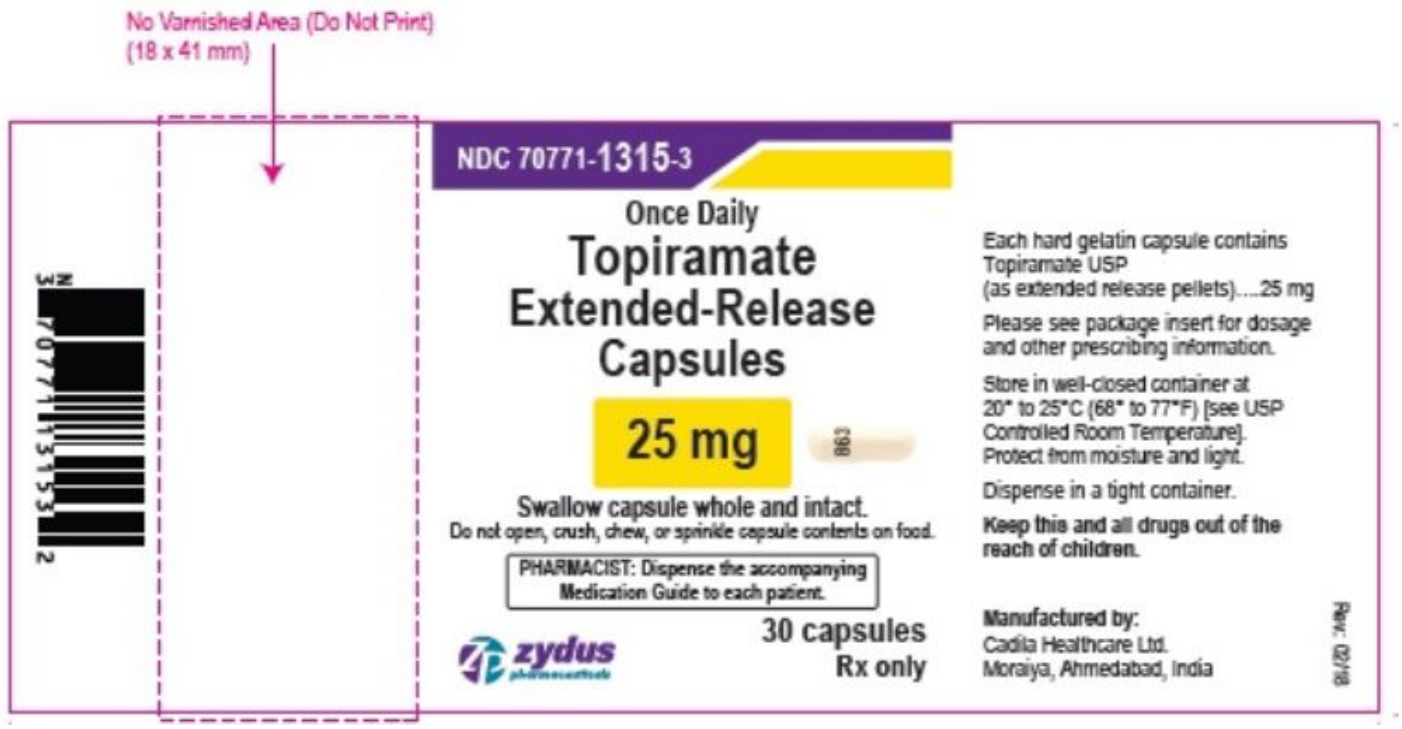
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1315-3

Topiramate extended-release capsules, 25 mg

30 capsules

Rx only

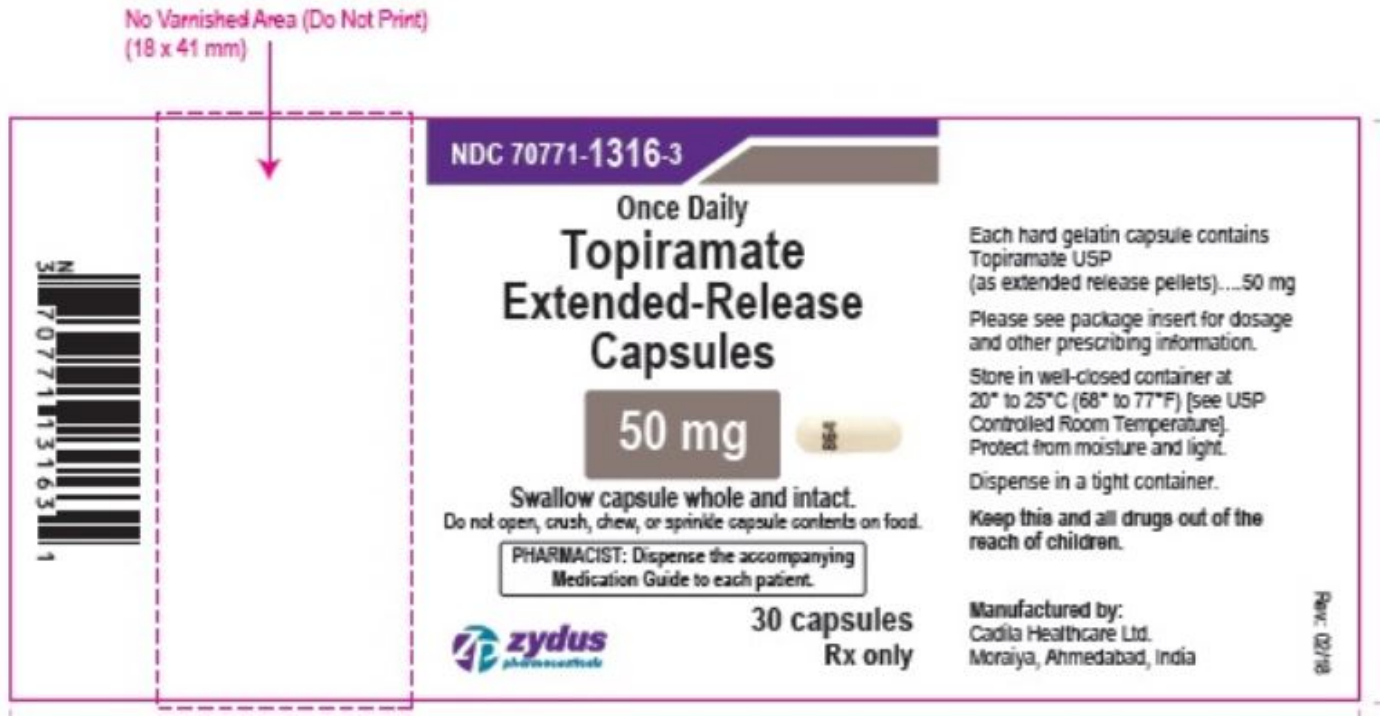


NDC 70771-1316-3

Topiramate extended-release capsules, 50 mg

30 capsules

Rx only

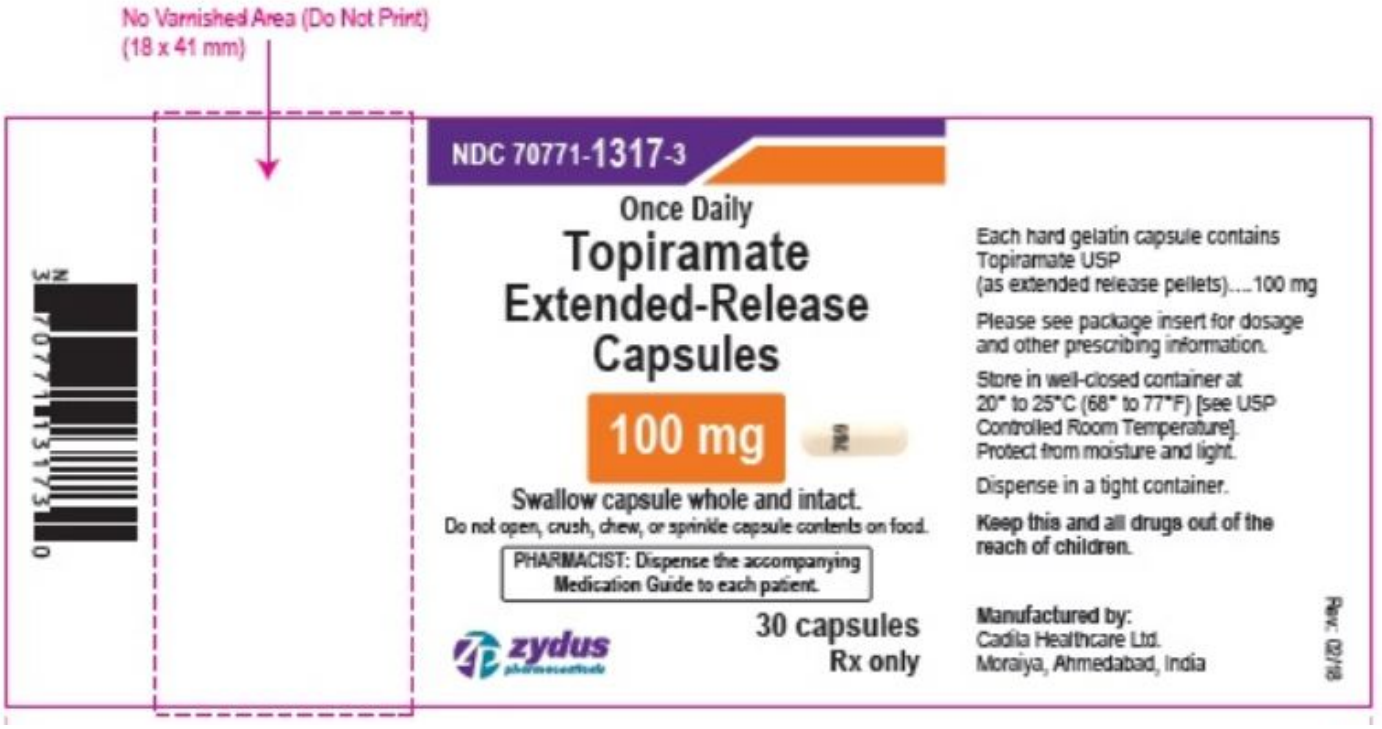


NDC 70771-1317-3

Topiramate extended-release capsules, 100 mg

30 capsules

Rx only

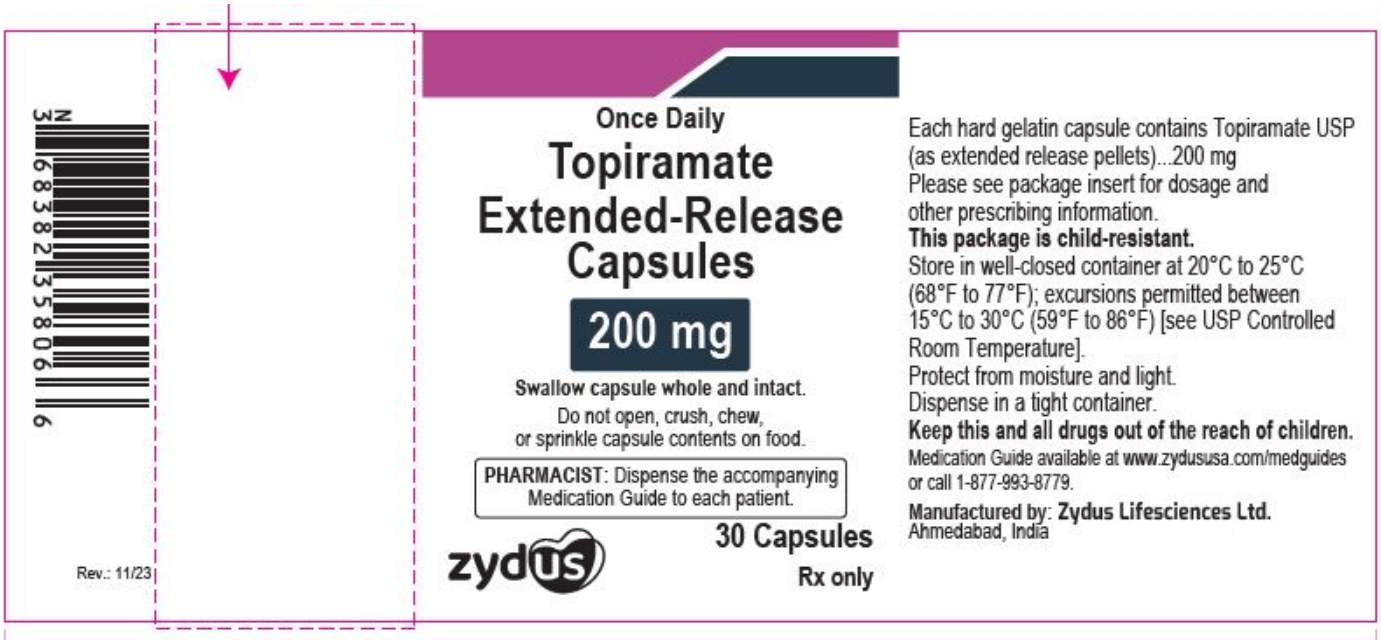


NDC 70771-1858-3

Topiramate extended-release capsules, 200 mg

30 capsules

Rx only



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: 0H73WJJ391) (TOPIRAMATE - UNII:0H73WJJ391)	TOPIRAMATE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POVIDONE (UNII: FZ989GH94E)	

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

Product Characteristics

Color	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	863
Contains			

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

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1316
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, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
GELATIN (UNII: 2G86QN327L)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	864
Contains			

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			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1317
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**
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	**Score**	no score
Shape	CAPSULE	**Size**	23mm
Flavor		**Imprint Code**	769
Contains			

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

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1858
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (WHITE OPAQUE) , WHITE (WHITE OPAQUE)	**Score**	no score
Shape	CAPSULE	**Size**	24mm
Flavor		**Imprint Code**	358
Contains			

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