LEVETIRACETAM- levetiracetam tablet, film coated
Zydus Lifesciences Limited

LEVETIRACETAM TABLETS

Manufactured by:

Cadila Healthcare Ltd.

India

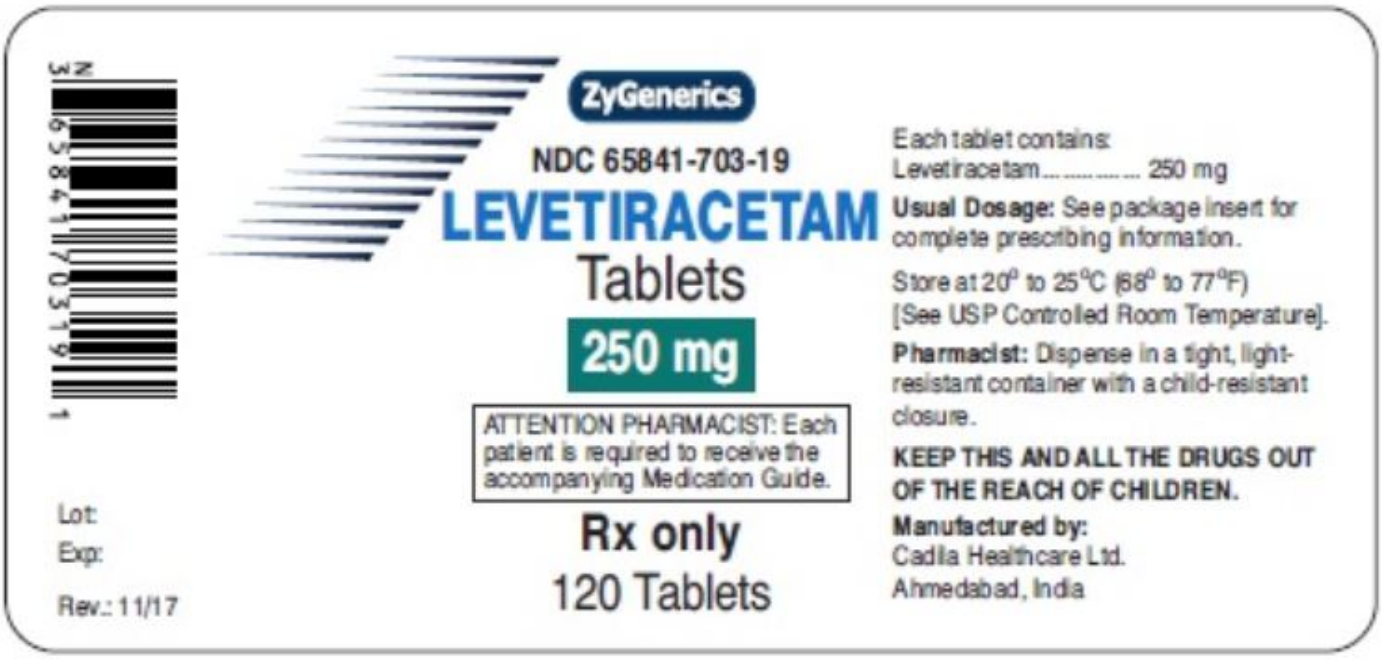
SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-703-19 in bottle of 120 tablets

Levetiracetam Tablets, 250 mg

Rx only

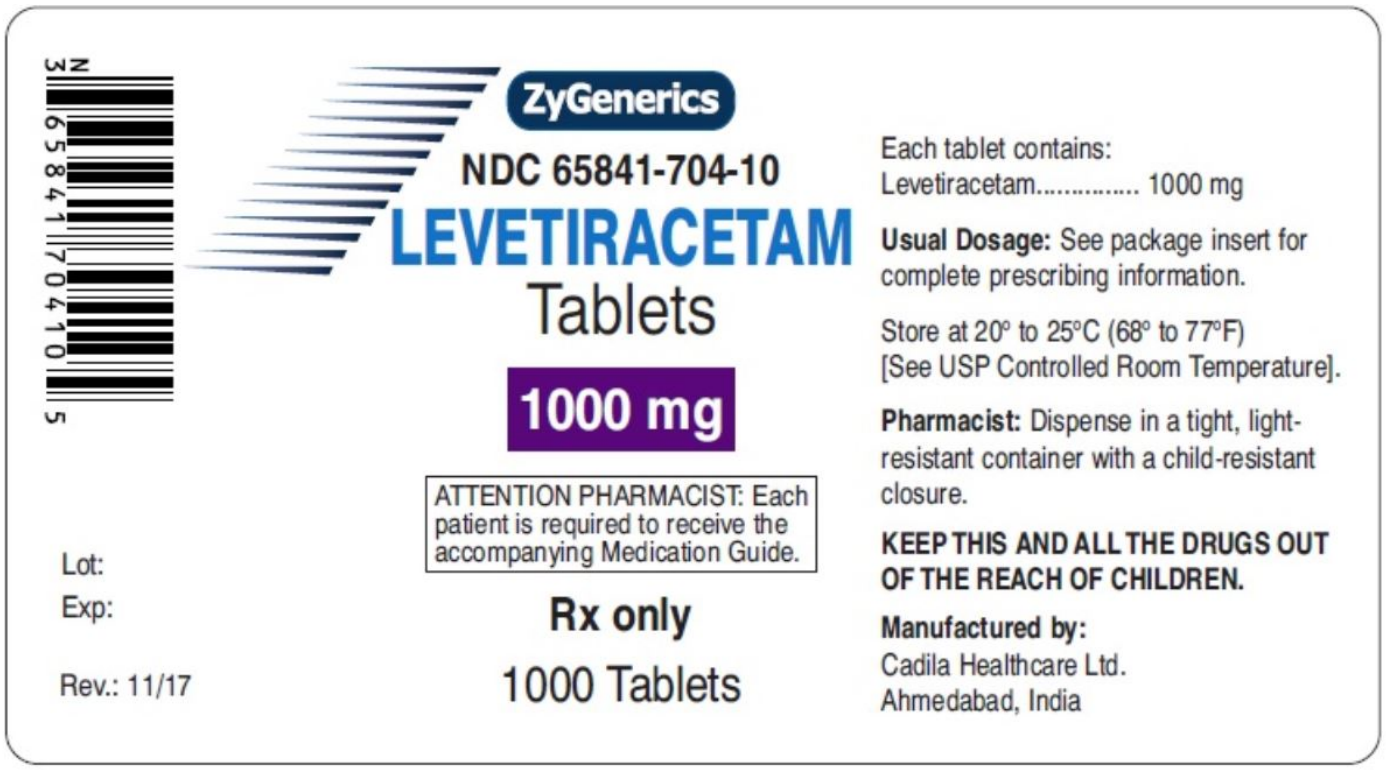


NDC 65841-704-10

Levetiracetam Tablets, 1000 mg

1000 tablets

Rx only



LEVETIRACETAM

levetiracetam tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-703
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVETIRACETAM (UNII: 44YRR34555) (LEVETIRACETAM - UNII:44YRR34555)	LEVETIRACETAM	250 mg

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	13mm
Flavor		**Imprint Code**	ZE;32
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-703-19	120 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:65841-703-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:65841-703-77	10 in 1 CARTON	12/05/2017	
3		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	ANDA078918	12/05/2017	

LEVETIRACETAM

levetiracetam tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-704
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVETIRACETAM (UNII: 44YRR34555) (LEVETIRACETAM - UNII:44YRR34555)	LEVETIRACETAM	1000 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	21mm
Flavor		**Imprint Code**	ZE;35
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-704-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
2	NDC:65841-704-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2017	
3	NDC:65841-704-77	10 in 1 CARTON	12/05/2017	
3		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	ANDA078918	12/05/2017	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-703, 65841-704) , MANUFACTURE(65841-703, 65841-704)

Revised: 11/2024 Zydus Lifesciences Limited