

LEVETIRACETAM- levetiracetam tablet, film coated
Zydus Lifesciences Limited

LEVETIRACETAM TABLETS

Manufactured by:

Cadila Healthcare Ltd.

India

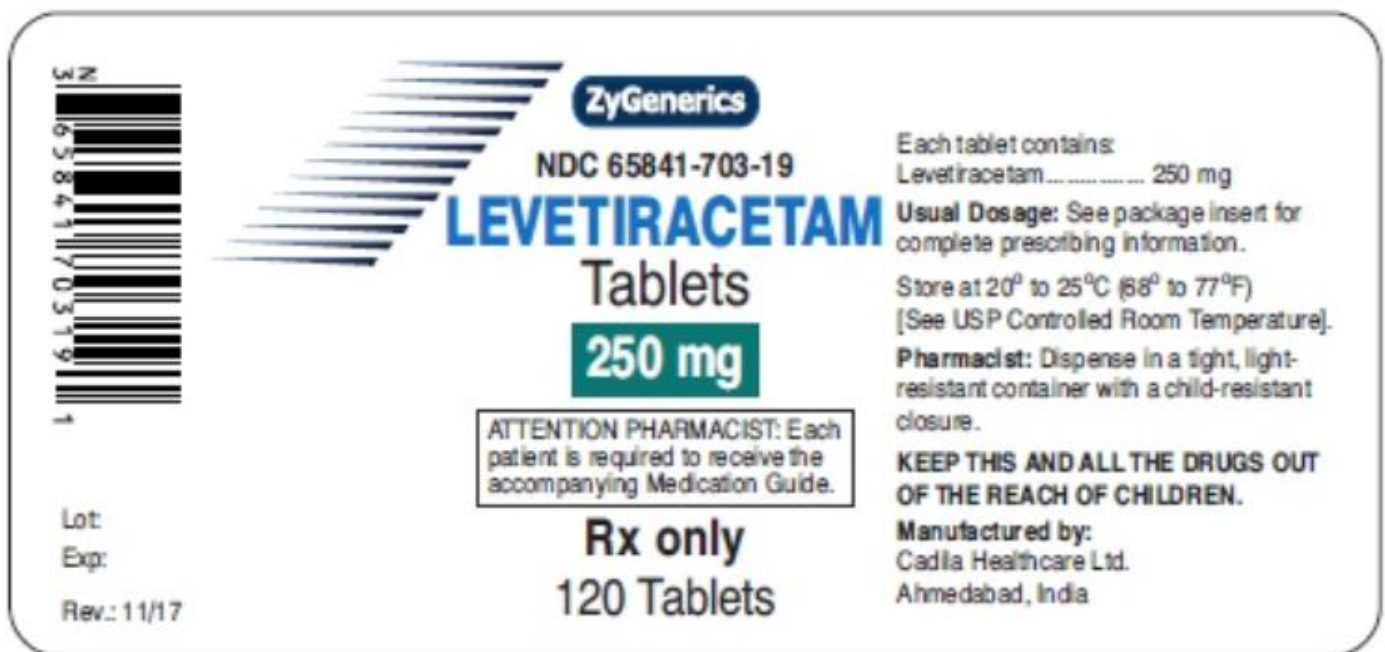
SPL MEDGUIDE

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



ZyGenerics

NDC 65841-704-10

LEVETIRACETAM
Tablets

1000 mg

ATTENTION PHARMACIST: Each patient is required to receive the accompanying Medication Guide.

Lot:

Exp:

Rev.: 11/17

Rx only

1000 Tablets

Each tablet contains:
Levetiracetam..... 1000 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].

Pharmacist: Dispense in a tight, light-resistant container with a child-resistant closure.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

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: 70097M6I3O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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: 3WJQ0SDW1A)	
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: 9/2023

Zydus Lifesciences Limited