

DIVALPROEX SODIUM- divalproex sodium tablet, delayed release
Zydus Lifesciences Limited

DIVALPROEX SODIUM DELAYED-RELEASE TABLETS safely

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-634-01 in bottle of 100 tablets

Divalproex Sodium Delayed-release Tablets USP, 125 mg

Rx only

100 tablets



NDC 65841-635-01 in bottle of 100 tablets

Divalproex Sodium Delayed-release Tablets USP, 250 mg

Rx only

100 tablets

No Varnished Area (Do Not Print)
(18 x 41 mm)

NDC 65841-635-01

**Divalproex Sodium
Delayed-release
Tablets, USP**

250 mg ZA07

(Valproic Acid Activity)

PHARMACIST: Dispense the Medication Guide
provided separately to each patient.

100 TABLETS
Rx only

Each tablet contains:
Divalproex sodium, USP equivalent to
valproic acid 250 mg

Usual Dosage: See package insert for
full prescribing information.

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

Dispense in light-resistant container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 11/18

NDC 65841-636-01 in bottle of 100 tablets

Divalproex Sodium Delayed-release Tablets USP, 500 mg

Rx only

100 tablets

No Varnished Area (Do Not Print)
(18 x 50.5 mm)

NDC 65841-636-01

**Divalproex Sodium
Delayed-release
Tablets, USP**

500 mg

(Valproic Acid Activity)

PHARMACIST: Dispense the Medication Guide
provided separately to each patient.

zydus
pharmaceuticals

100 TABLETS
Rx only

Each tablet contains:
Divalproex sodium, USP equivalent to
valproic acid 500 mg

Usual Dosage: See package insert for
full prescribing information.

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

Dispense in light-resistant container.

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

Manufactured by:
Cadila Healthcare Ltd.
Ahmedabad, India

Rev: 11/18

DIVALPROEX SODIUM

divalproex sodium tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-634
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIVALPROEX SODIUM (UNII: 644VL95AO6) (VALPROIC ACID - UNII:614O11Z5W)	VALPROIC ACID	125 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POVIDONE (UNII: FZ989GH94E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B71O)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STARCH, CORN (UNII: O8232NY3SJ)
TALC (UNII: 7SEV7J4R1U)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	12mm
Flavor		Imprint Code	ZA08
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-634-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2010	
2	NDC:65841-634-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077100	03/06/2010	

DIVALPROEX SODIUM

divalproex sodium tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-635
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIVALPROEX SODIUM (UNII: 644VL95AO6) (VALPROIC ACID - UNII:614O11Z5W)	VALPROIC ACID	250 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	

BUTYL ALCOHOL (UNII: 8PJ61P6TS3)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
HYPROMELLOSES (UNII: 3NXW29V3WO)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
MAGNESIUM STEARATE (UNII: 70097M6I30)
METHACRYLIC ACID (UNII: 1CS02G8656)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE (UNII: FZ989GH94E)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SHELLAC (UNII: 46N107B710)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STARCH, CORN (UNII: O8232NY3SJ)
TALC (UNII: 7SEV7J4R1U)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	14mm
Flavor		Imprint Code	ZA07
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-635-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2010	
2	NDC:65841-635-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077100	03/06/2010	

DIVALPROEX SODIUM

divalproex sodium tablet, delayed release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-636
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIVALPROEX SODIUM (UNII: 644VL95AO6) (VALPROIC ACID - UNII:614O11Z5W)	VALPROIC ACID	500 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE (WHITE TO OFF WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	19mm
Flavor		Imprint Code	ZA06
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-636-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2010	
2	NDC:65841-636-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077100	03/06/2010	

Registrant - Zydus Lifesciences Limited (918596198)**Establishment**

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-634, 65841-635, 65841-636) , MANUFACTURE(65841-634, 65841-635, 65841-636)

Revised: 9/2023

Zydus Lifesciences Limited