

**DIVALPROEX SODIUM- divalproex sodium tablet, delayed release**  
**Cadila Healthcare Limited**

-----  
**DIVALPROEX SODIUM DELAYED-RELEASE TABLETS safely**

**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**

(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.

**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

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

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
DIVALPROEX SODIUM (UNII: 644VL95AO6) (VALPROIC ACID - UNII:614OI1Z5WI)	VALPROIC ACID	125 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

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

## 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:614O11Z5WI)	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: 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	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:614O11Z5W1)	VALPROIC ACID	500 mg

### Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERROSO FERRIC 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

<b>Flavor</b>		<b>Imprint Code</b>	ZA06	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
ANDA	ANDA077100	03/06/2010		

**Labeler** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

### Establishment

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

Revised: 8/2020

Cadila Healthcare Limited