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

NDC 65841-636-01 in bottle of 100 tablets

Divalproex Sodium Delayed-release Tablets USP, 500 mg

Rx only

100 tablets

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:614OI1Z5WI)	VALPROIC ACID	125 mg

Inactive Ingredients	
Ingredient Name	**Strength**
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERROSOFERRIC 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:614OI1Z5WI)	VALPROIC ACID	250 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FERROSOFERRIC 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:614OI1Z5WI)	VALPROIC ACID	500 mg

Inactive Ingredients

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

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