DIVALPROEX SODIUM - divalproex sodium tablet, film coated, extended release
Zydus Lifesciences Limited

DIVALPROEX SODIUM EXTENDED-RELEASE TABLETS

SPL MEDGUIDE

Manufactured by:

Cadila Healthcare Ltd.

India.

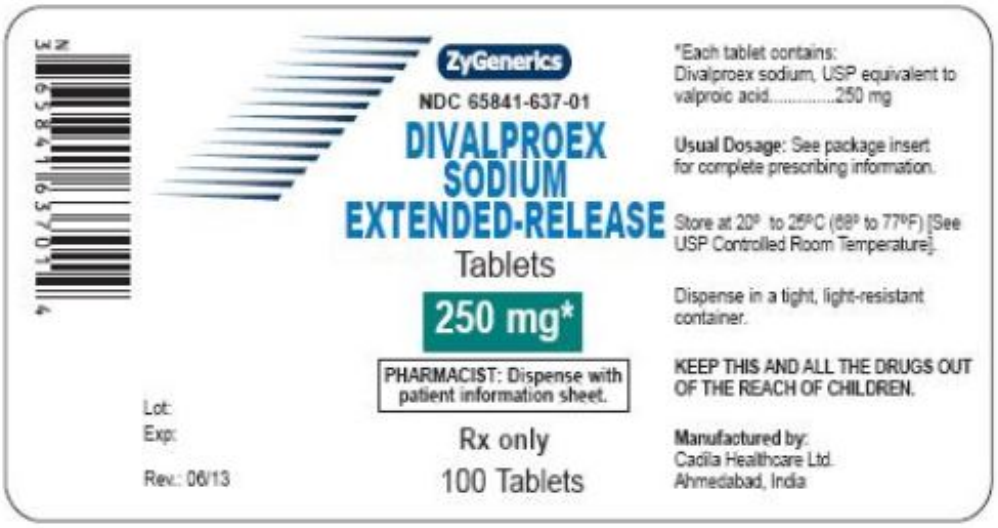
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-637-01 in bottle of 100 tablets

Divalproex Sodium ER Tablets, 250 mg

Rx only

100 tablets



NDC 65841-638-01 in bottle of 100 tablets

Divalproex Sodium ER Tablets, 500 mg

Rx only

100 tablets

DIVALPROEX SODIUM

divalproex sodium tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-637
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	ZA47
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-637-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	
2	NDC:65841-637-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	
3	NDC:65841-637-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	
4	NDC:65841-637-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078239	01/07/2013	

DIVALPROEX SODIUM

divalproex sodium tablet, film coated, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-638
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)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	23mm
Flavor		**Imprint Code**	ZA48
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-638-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	
2	NDC:65841-638-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	
3	NDC:65841-638-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/07/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078239	01/07/2013	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-637, 65841-638) , MANUFACTURE(65841-637, 65841-638)

Revised: 10/2022 Zydus Lifesciences Limited