DIVALPROEX SODIUM- divalproex sodium capsule, coated pellets
Zydus Lifesciences Limited

DIVALPROEX SODIUM DELAYED-RELEASE CAPSULES

SPL MEDGUIDE

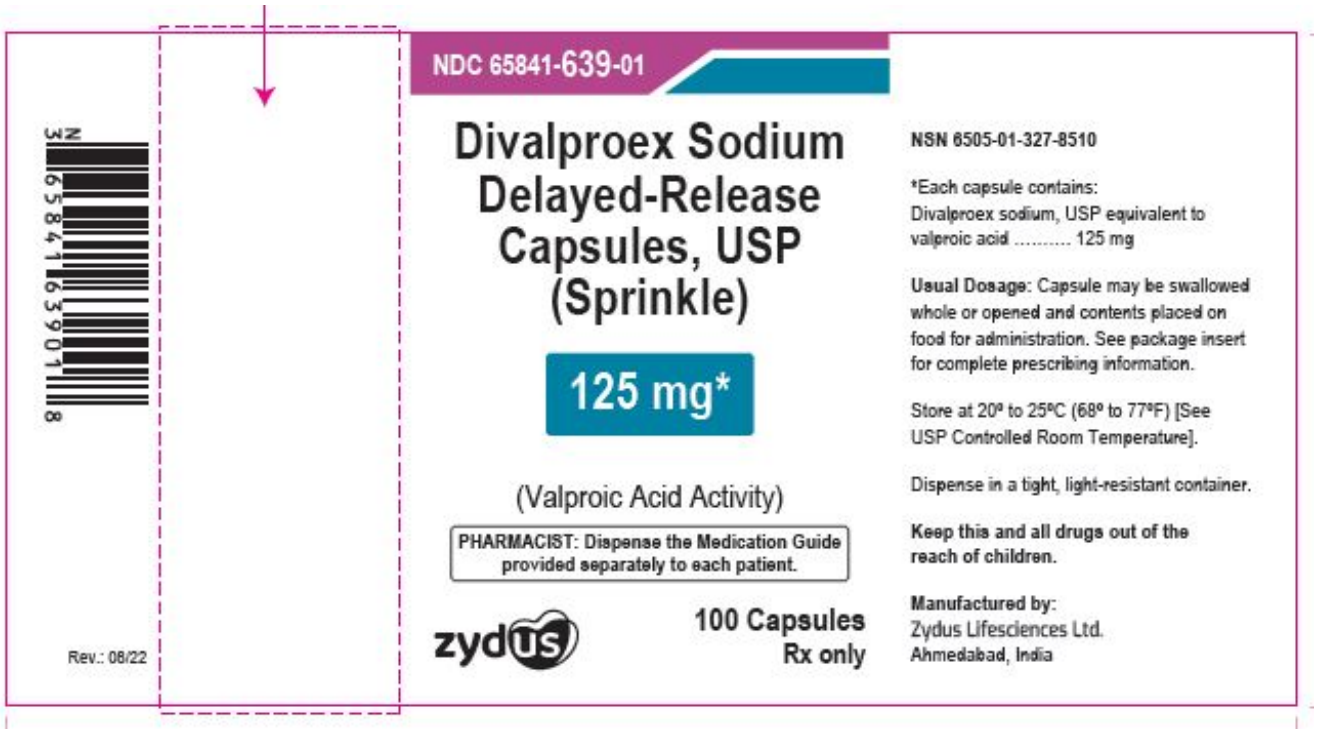
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-639-01 in bottle of 100 Capsules

Divalproex sodium delayed-release capsules, USP (sprinkle)

Rx only

100 capsules



DIVALPROEX SODIUM

divalproex sodium capsule, coated pellets

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-639
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
ALCOHOL (UNII: 3K9958V90M)	
AMMONIA (UNII: 5138Q19F1X)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHACRYLIC ACID (UNII: 1CS02G8656)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BLUE (BLUE) , WHITE (WHITE)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	22mm
Flavor		**Imprint Code**	ZA66;125mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-639-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
2	NDC:65841-639-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-639-30	10 in 1 CARTON	01/27/2009	
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	ANDA078919	01/27/2009	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-639) , MANUFACTURE(65841-639)

Revised: 9/2023 Zydus Lifesciences Limited