GABAPENTIN- gabapentin tablet, film coated
Zydus Lifesciences Limited

GABAPENTIN TABLETS

Manufactured by:

Cadila Heathcare Ltd.

India

SPL MEDGUIDE

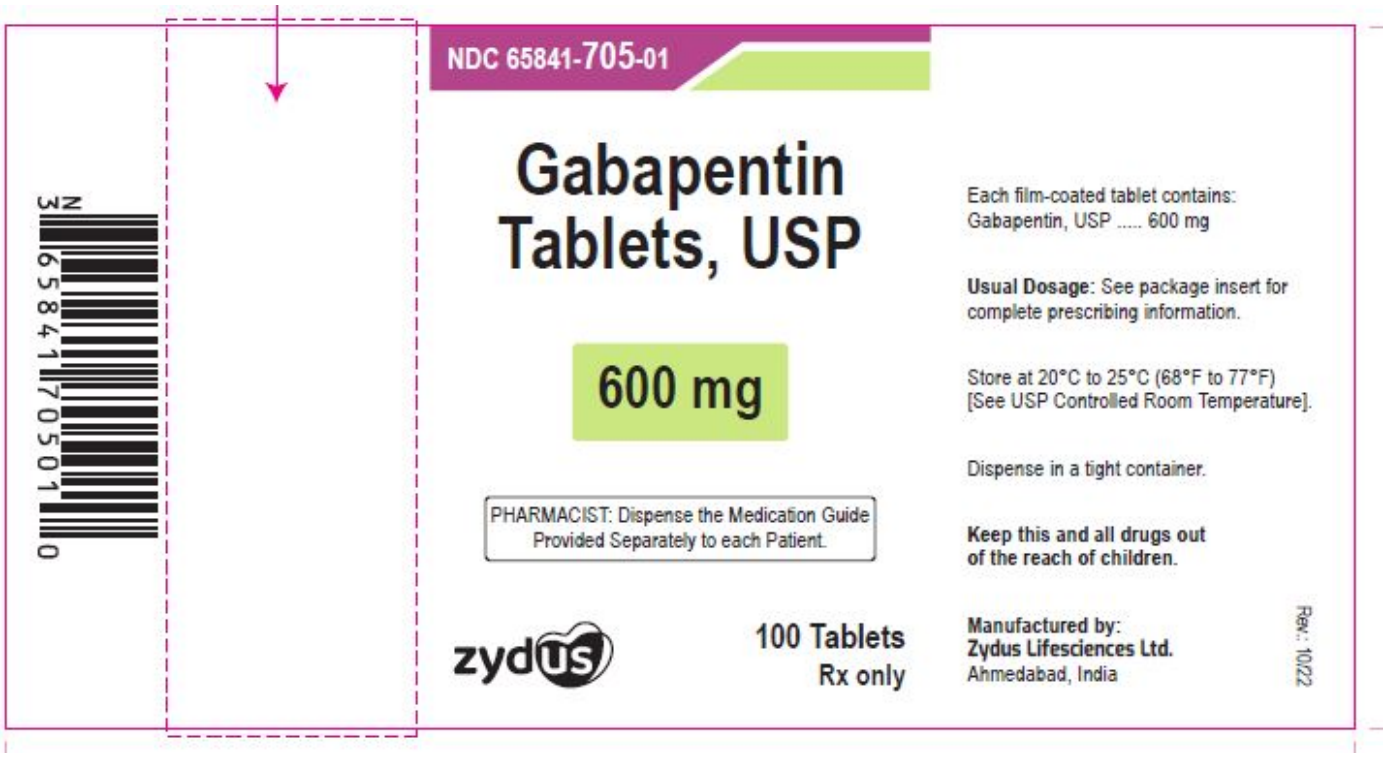
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-705-01 in bottle of 100 tablets

Gabapentin Tablets USP, 600 mg

R_x only

100 tablets

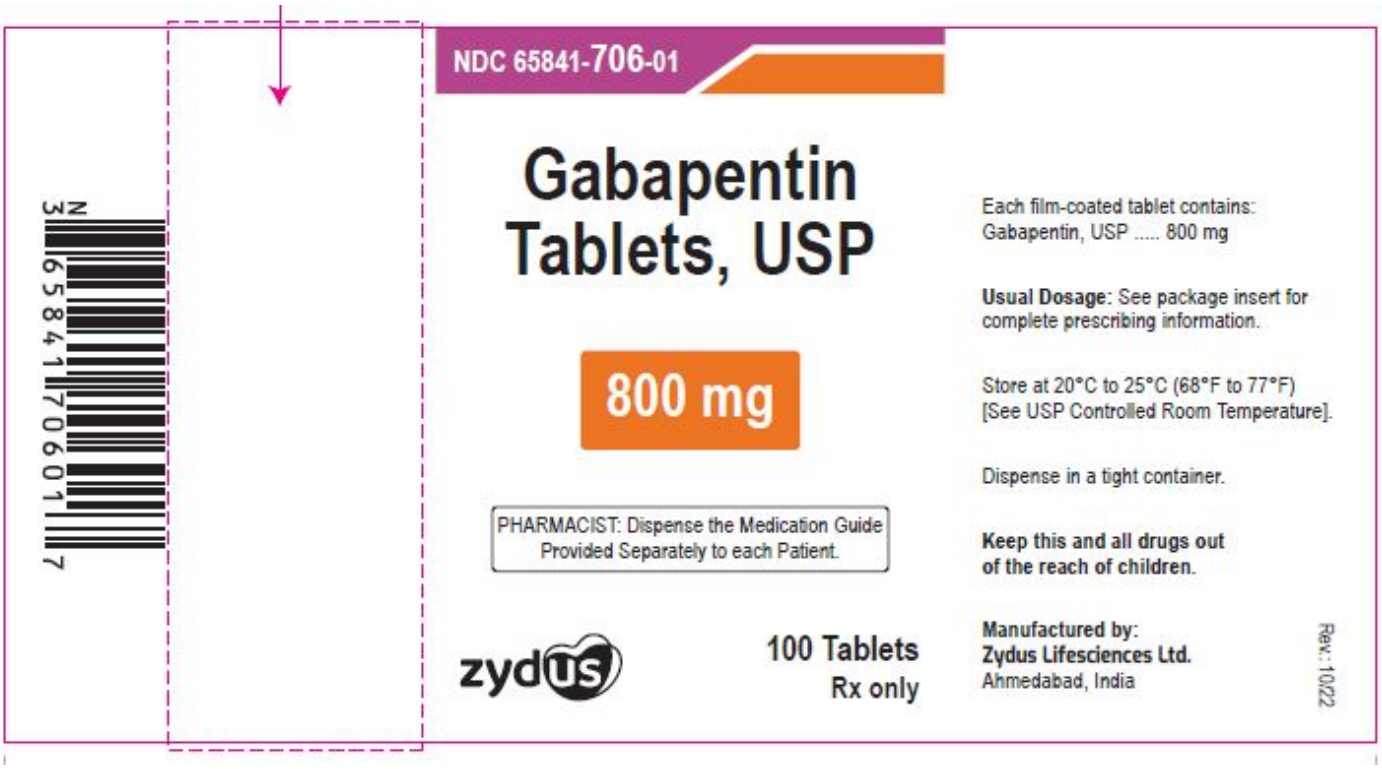


NDC 65841-706-01 in bottle of 100 tablets

Gabapentin Tablets USP, 800 mg

R_x only

100 tablets



GABAPENTIN

gabapentin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-705
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	600 mg

Inactive Ingredients	
Ingredient Name	**Strength**
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	17mm
Flavor		**Imprint Code**	ZE72
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-705-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2012	
2	NDC:65841-705-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2012	
3	NDC:65841-705-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078926	10/16/2012	

GABAPENTIN

gabapentin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-706
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	800 mg

Inactive Ingredients	
Ingredient Name	**Strength**
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED (UNII: 2165RE0K14)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POVIDONE (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	2 pieces
Shape	OVAL (OVAL)	**Size**	20mm
Flavor		**Imprint Code**	ZE71
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-706-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2012	
2	NDC:65841-706-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2012	
3	NDC:65841-706-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2012	
4	NDC:65841-706-77	10 in 1 CARTON	10/16/2012	
4		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	ANDA078926	10/16/2012	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-705, 65841-706) , MANUFACTURE(65841-705, 65841-706)

Revised: 9/2023 Zydus Lifesciences Limited