

GABAPENTIN- gabapentin tablet
Zydus Lifesciences Limited

Gabapentin Tablets

SPL UNCLASSIFIED

SPL MEDGUIDE

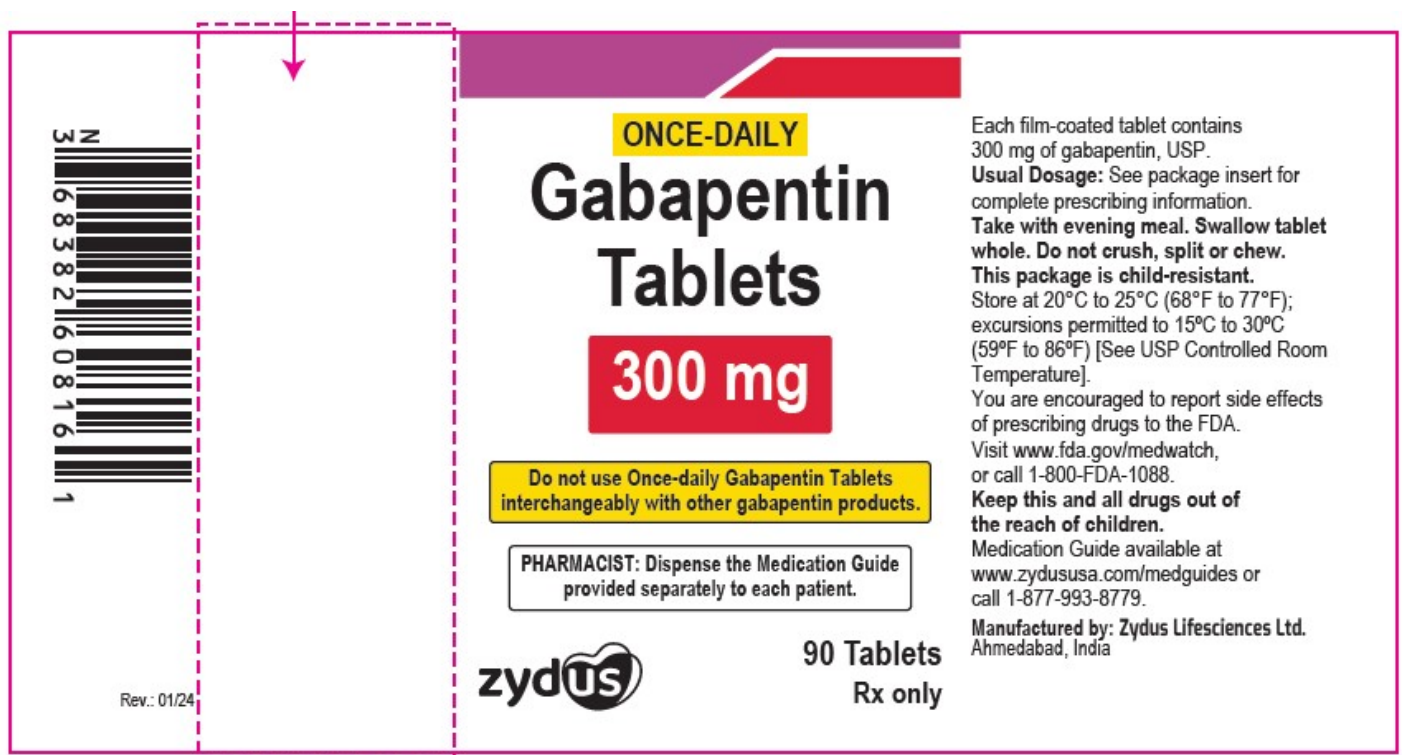
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1861-9 in bottle of 90 tablets

Gabapentin tablets, 300 mg

Rx only

90 tablets



gabapentin 300 mg

NDC 70771-1862-9 in bottle of 90 tablets

Gabapentin tablets, 600 mg

Rx only

90 tablets

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Rev.: 01/24

ONCE-DAILY
Gabapentin
Tablets
600 mg

Do not use Once-daily Gabapentin Tablets interchangeably with other gabapentin products.

PHARMACIST: Dispense the Medication Guide provided separately to each patient.

zydus

90 Tablets
Rx only

Each film-coated tablet contains 600 mg of gabapentin, USP.
Usual Dosage: See package insert for complete prescribing information.
Take with evening meal. Swallow tablet whole. Do not crush, split or chew. This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].
You are encouraged to report side effects of prescribing drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
Keep this and all drugs out of the reach of children.
Medication Guide available at www.zydususa.com/medguides or call 1-877-993-8779.
Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India

gabapentin 600 mg

GABAPENTIN

gabapentin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1861
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	300 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE)	
POLYETHYLENE GLYCOL 7000000 (UNII: G3MS6M810Y)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	608
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1861-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2024	
2	NDC:70771-1861-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2024	
3	NDC:70771-1861-2	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/25/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203934	01/25/2024	

GABAPENTIN

gabapentin tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1862
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
HYPROMELLOSE 2208 (100000 MPA.S) (UNII: VM7F0B23ZI)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 3OIQX730WE)	

POLYETHYLENE GLYCOL 7000000 (UNII: G3MS6M810Y)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	607
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1862-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2024	
2	NDC:70771-1862-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2024	
3	NDC:70771-1862-4	10 in 1 CARTON	01/25/2024	
3	NDC:70771-1862-2	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	ANDA203934	01/25/2024	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1861, 70771-1862) , MANUFACTURE(70771-1861, 70771-1862)

Revised: 1/2024

Zydus Lifesciences Limited