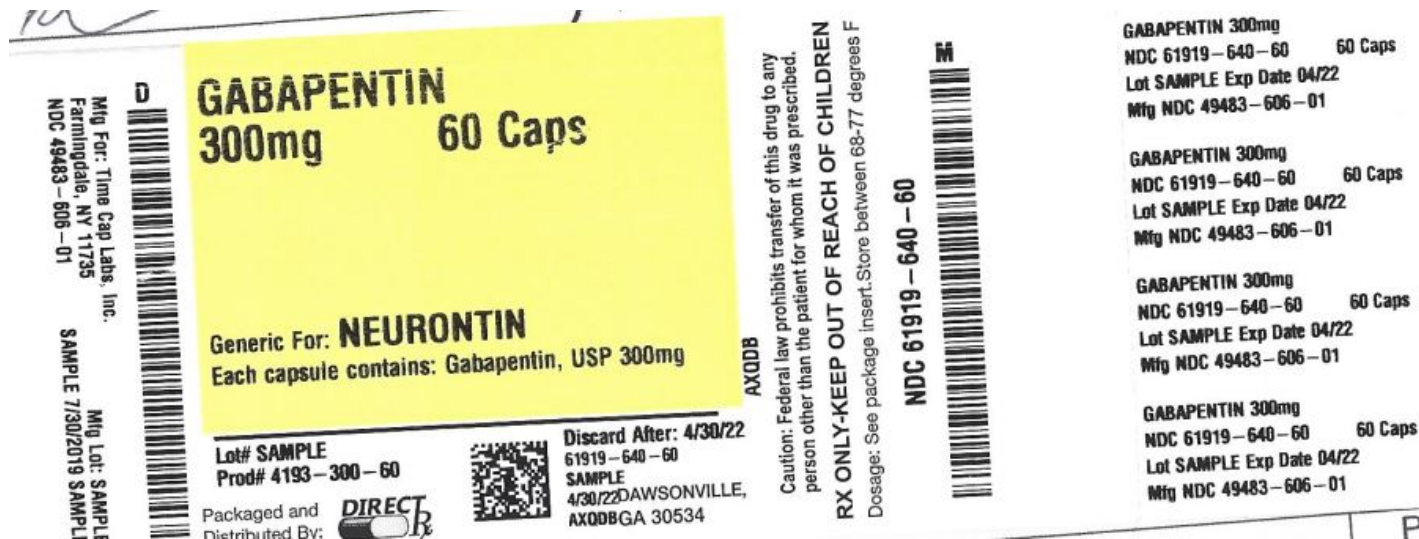


GABAPENTIN- gabapentin capsule
Direct_Rx

GABAPENTIN

100 mg Capsules (White/White colored, size '3' hard gelatin capsules with "103" printed on body of capsules containing white to off white granular powder) Bottles of 100 & 500
 300 mg Capsules (Yellow/Yellow colored, size '1' hard gelatin capsules with "104" printed on body of capsules containing white to off white granular powder) Bottles of 100 & 500
 400 mg Capsules (Orange/Orange colored, size '0' hard gelatin capsules with "105" printed on body of capsules containing white to off white granular powder) Bottles of 100 & 500



GABAPENTIN			
gabapentin capsule			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-640(NDC:49483-606)
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SHELLAC (UNII: 46N107B71O)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
STARCH, CORN (UNII: O8232NY3SJ)			

TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	yellow	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	104
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-640-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090007	08/08/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(61919-640)

Revised: 8/2019

Direct_Rx