GABAPENTIN - gabapentin capsule
Alivio Medical Products, LLC

Drug Facts

Each capsule contains:

300 mg of gabapentin, USP.

Dosage and Use:

See package insert

for full prescribing information

Store at 20 to 25 C (68 to 77 F); excursions

permitted to 15 to 30 C (59 to 86 F)) [See

USP Controlled Room Temperature].

Dispense in tight (USP), child-resistant containers.

Pharmacist: Please dispense

with medication guide

provided separately

Highlights of Prescribing Information

T**hese highlights do not include all the information needed to use gabapentin capsules safely and effectively. See full prescribing information for gabapentin capsules**.

GABAPENTIN capsules, USP for oral use

Initial U.S. Approval: 1993

FULL PRESCRIBING INFORMATION: CONTENTS

Gabapentin capsules, USP, are indicated for:

-management of postherpeticneuralgia in adults

-Adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy

DOSAGE AND ADMINISTRATION

Gabapentin capsules, USP are given orally with or without food. Gabapentin capsules, USP should be swallowed whole with plenty of water.

DOSAGE FORMS AND STRENGTHS

Capsules:

- 100 mg; white-white, opague hard gelatin capsules printed with "IP 101 " on both cap and body.
- 300 mg: buff-buff, opague hard gelatin capsules printed with "IP 102" on both cap and body.
- 400 mg: light caramel-light caramel, opague hard gelatin capsules printed with "IP 103" on both cap and body

CONTRAINDICATIONS

Gabapentin capsules, USP are contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients.

WARNINGS AND PRECAUTIONS

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) Multiorgan Hypersensitivity

Drug Reaction with with Eosinophilia and Systemic Symptoms

ADVERSE REACTIONS

The following severe adverse reactions are discussed in greater detail in other sections: Drug Reaction

with Eosiniphilia and Systemic Syndrome (DRESS) Multiorgan

DRUG INTERACTIONS

Other Antiepileptic Drugs Gabapentin is not appreciably metabolized nor does it interfere

with the metabolism of commonly co-administered antiepileptic drugs

USE IN SPECIFIC POPULATIONS

Pregnanacy - Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women.

DRUG ABUSE AND DEPENDENCE

Controlled Substance - Gabapentin is not a scheduled drug.

OVERDOSAGE

A lethal dose of gabapentin was not identified in mice and rats receiving single oral doses as high as 8000 mg / kg.

DESCRIPTION

The active ingredient in gabapentin capsules, USP is gabapentin which has the chemical name 1-(aminoethyl) cyclohexaneacetic acid.

CLINICAL PHARMACOLOGY

Mechanism of Action - The precise mechanisms by which gabapentin produces its analgesic and antiepileptic actions are unknown.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility - Gabapentin was adminstered orally to mice and rats in 2-year carcinogenicity studies.

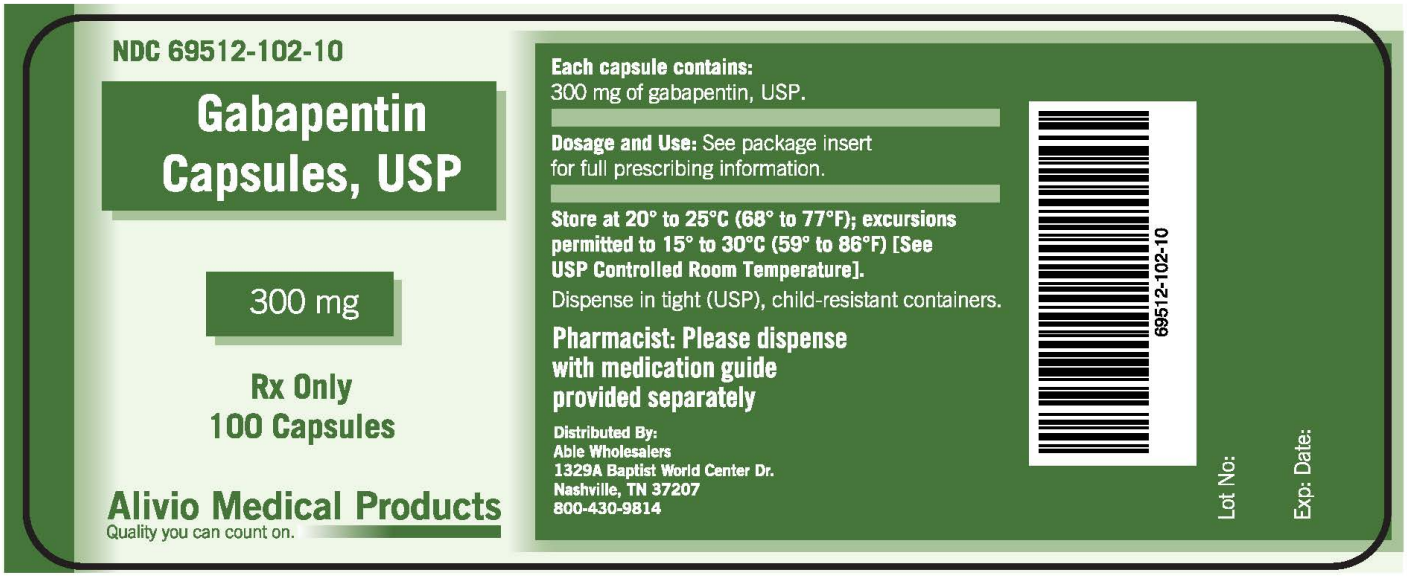
CLINICAL STUDIES

Postherpetic Neuralgia Gabapentin was evaluated for the management of postherpetic neuralgia (PHN) in two randomized, double-blind, placebo-controlled multicenter studies.

HOW SUPPLIED/STORAGE AND HANDLING

Gabapentin capsules, USP

PATIENT COUNSELING INFORMATION



GABAPENTIN

gabapentin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69512-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GABAPENTIN (UNII: 6CW7F3G59X) (GABAPENTIN - UNII:6CW7F3G59X)	GABAPENTIN	300 mg in 300 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	yellow (Yellow (buff buff))	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	IP102
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69512-102-10	100 in 1 BOTTLE		
1		300 mg in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078428	10/01/2015	

Labeler - Alivio Medical Products, LLC (079670828)

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