URGENT NOTICE

TYPE: RECALL

Complaints of Empty Capsules

Drug Name: **Gabapentin Capsules, USP 300 mg, by Aurobindo Pharma**

Audience: Neurology, Risk Manager, Health Professionals, Pharmacy, and Nursing

Date: **11/24/2014**

ISSUE

Aurobindo Pharma USA is voluntarily recalling lot GESB14011-A of Gabapentin Capsules, USP 300 mg 100-count bottles to the consumer level. The product lot has been found to contain some empty capsules.

Empty capsules could result in missed dose(s) of gabapentin resulting in adverse health consequences that could range from no effect, short term reduction in efficacy, short term withdrawal effect, or status epilepticus (long period seizures) that could be life-threatening.

BACKGROUND

Gabapentin is used as in the treatment of epilepsy and for the management of post herpetic neuralgia (pain after shingles). The affected Gabapentin lot is GESB14011-A, Expiration 12/2015 and is packaged in 100-count bottles, NDC 16714-662-01. Product was distributed through Northstar label to retail outlets nationwide.

RECOMMENDATION

Consumers, distributors, and retailers that have product which is being recalled should stop using, distributing, or dispensing the affected lot and return to place of purchase. Consumers with questions regarding this recall can contact Aurobindo Pharma USA Pharmacovigilance group at (732) 839-9400, Option 2. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

For more information call (888) 463-6332 or visit FDA.gov.