COMPANY ANNOUNCEMENT

Aurobindo Pharma USA, Inc. Issues Voluntary Nationwide Recall of Mirtazapine Tablets Lot Number 03119002A3 Due to Label Error on Declared Strength

Summary

Company Announcement Date:

December 30, 2019

FDA Publish Date:

December 31, 2019

Product Type:

Drugs

Reason for Announcement:

Due to a label error on declared strength-bottles labeled as Mirtazapine 7.5 mg

Company Name:

Aurobindo Pharma USA, Inc.

Brand Name:

Aurobindo Pharma USA, Inc.

Product Description:

Mirtazapine Tablets 7.5 mg

Company Announcement

Aurobindo Pharma USA, Inc. is voluntarily recalling lot number 03119002A3 of Mirtazapine Tablets to the consumer level. The product is being recalled due to a label error on declared strength; bottles labeled as Mirtazapine 7.5 mg may contain 15 mg tablets.

Taking a higher dose than expected, may increase risk of sedation, agitation, increased reflexes, tremor, sweating, dilated pupils, gastrointestinal distress, nausea, constipation and more. Unexpected levels of sedation in particular can contribute to falls in the elderly or motor vehicle accidents in adults.

Mirtazapine tablets are indicated for the treatment of major depressive disorder and are packaged in 500 count bottles. The affected lot number for both Mirtazapine Tablets 7.5 mg and Mirtazapine Tablets 15 mg are 03119002A3 Exp 03/2022. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

Aurobindo Pharma USA, Inc. is notifying its distributors by letter and is arranging for return of all of the recalled product. Distributors/retailers that have product which is being recalled should return the bottle(s) to place of purchase.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Aurobindo Pharma USA, Inc. at:

- 1-866-850-2876 Option 2
- pvg@aurobindousa.com (mailto:pvg@aurobindousa.com)

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.

Any general **questions regarding the return of this product** please contact Qualanex at 1-888-504-2014 or email mecall@qualanex.com (mailto:mecall@qualanex.com)(live calls received 7:00 am to 4:00 pm M-F CST).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (file:///C:/node/360543) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- Regular Mail or Fax: Download form (file:///C:/node/360547) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Aurobindo Pharma USA

1-866-850-2876 Option 2

pvg@aurobindousa.com (mailto:pvg@aurobindousa.com)

Product Photos