Mirtazapine – Aurobindo Pharma USA

On December 30, 2019 the U.S. Food and Drug Administration (FDA) announced that Aurobindo Pharma USA, Inc. is voluntarily recalling one (1) lot of Mirtazapine Tablets due to a label error on declared strength; bottles labeled as Mirtazapine 7.5mg may contain 15mg 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. 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

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.