January 3,2020

COM-2020-002

Voluntary Nationwide Recall of Mirtazapine Tablets

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on December 31, 2019, the U.S. Food and Drug Administration (FDA) issued a statement that Aurobindo Pharma USA, Inc. is recalling **Mirtazapine Tablets (7.5mg and 15mg) lot number 03119002A3 with expiration date Exp 03/2022** to the consumer level due to a mislabel on product strength. Bottles with 7.5mg tablets may contain 15mg tablets.

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing it. Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.
2. Consumers: questions regarding this recall, refer to the following contact information:
   - Medical questions: Aurobindo Pharma USA, Inc.
     - Phone: 1-866-850-2876, Option 2 or pvg@aurobindousa.com
   - General questions:
     - Qualanex at 1-888-504-2014 or email mecall@qualanex.com

Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- Online: www.fda.gov/medwatch/report.htm

- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-issues-voluntary-nationwide-recall-mirtazapine-tablets-lot-number

Clinical Department