Aurobindo – Recall of mirtazapine

- On December 31, 2019, Aurobindo announced a consumer-level recall of one lot of mirtazapine tablets due to a label error on declared strength. Bottles labeled as mirtazapine 7.5 mg may contain 15 mg tablets.

Product Description	NDC #	Lot # (expiration date)
Mirtazapine, 7.5 mg tablets, 500-count bottles	13107-001-05	03119002A3 (3/2022)

- Mirtazapine tablets are indicated for the treatment of major depressive disorder.
- Taking a higher dose of mirtazapine 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.
- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related using the recalled mirtazapine.
- Anyone with an existing inventory of the recalled product should quarantine and discontinue distribution of the product immediately.
- Contact Qualanex (appointed company for Aurobindo) at **1-888-504-2014** or email **mecall@qualanex.com** for further information regarding this recall.