AuroMedics – Recall of levetiracetam, levofloxacin and linezolid injection products

- On April 5, 2018, AuroMedics announced a user-level recall of all remaining unexpired lots of levetiracetam, levofloxacin, and linezolid injection products due to leaking bags.
    - Finished product release testing for both sterility and endotoxin was acceptable for all product lots and there have been no confirmed bag integrity-related complaints for the recalled products.

Product Description	NDC #
Levetiracetam in 0.82% sodium chloride injection, 500 mg/100 mL (5 mg/mL)	55150-246-47
Levetiracetam in 0.75% sodium chloride injection, 1000 mg/100 mL (10 mg/mL)	55150-247-47
Levetiracetam in 0.54% sodium chloride injection, 1500 mg/100 mL (15 mg/mL)	55150-248-47
Levofloxacin in 5% dextrose injection, 250 mg/50 mL	55150-243-46
Levofloxacin in 5% dextrose injection, 500 mg/100 mL	55150-244-47
Levofloxacin in 5% dextrose injection, 750 mg/150 mL	55150-245-52
Linezolid 600 mg/300 mL (2 mg/mL) injection	55150-242-51

- Levetiracetam is indicated as adjunctive therapy for adults (16 years and older) when oral administration is not feasible for the following: partial onset seizures; myoclonic seizures in patients with juvenile myoclonic epilepsy; and primary generalized tonic-clonic seizures.

- Levofloxacin is indicated for the treatment of adults with mild, moderate, and severe infections caused by susceptible isolates of certain microorganisms in nosocomial and community-acquired pneumonia; complicated and uncomplicated skin and skin structure infections; chronic bacterial prostatitis; inhalational anthrax; plague; complicated and uncomplicated urinary tract infections; acute pyelonephritis; acute bacterial exacerbation of chronic bronchitis; and acute bacterial sinusitis.

- Linezolid is indicated for the treatment of infections caused by susceptible strains of certain microorganisms in pneumonia, skin and skin structure infections, and vancomycin-resistant *Enterococcus faecium* infections.

- To date, AuroMedics has not received any reports of adverse events related to these products but is issuing this recall out of an abundance of caution.

- Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using any of the recalled products.

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- Anyone with recalled product should immediately quarantine and discontinue distribution of the recalled product. Contact AuroMedics Customer Service at **1-888-238-7880** for more information regarding this recall.