Claris Lifesciences – Recall of injectable products

- On March 10, 2017, Claris Lifesciences announced a user-level recall of some lots of fluconazole, ciprofloxacin, levofloxacin, and metronidazole injectable products due to the potential of a leak from the primary container, which may have resulted from shipping damage and which may result in a potential breach of sterility and contamination of the contents.

- Affected products were distributed between December 4, 2015 and May 26, 2016.

Product Description	NDC #	Lot # (Expiration date)
Fluconazole injection, USP iso- osmotic sodium chloride diluent 400 mg in 200 mL	36000-003-06	A051052 (8/2017)
Ciprofloxacin in dextrose (5%) injection, USP 400 mg in 200 mL 5% dextrose	36000-009-24	A051288 (9/2017)
Levofloxacin injection in 5% dextrose, 750 mg in 150 mL 5% dextrose	36000-048-24	A060040 (12/2017)
Metronidazole injection, USP 500 mg/100 mL	36000-001-24	A060205 (1/2018), A060209 (1/2018)

- Fluconazole injection is indicated for the treatment of oropharyngeal and esophageal candidiasis; cryptococcal meningitis; and to decrease the incidence of candidiasis in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.

- Ciprofloxacin injection is indicated for the treatment of the following infections caused by designated, susceptible bacteria where indicated: skin and skin structure infections, bone and join infections, complicated intra-abdominal infections, nosocomial pneumonia, empirical therapy for febrile neutropenic patients, inhalation anthrax (post-exposure), plague, chronic bacterial prostatitis, lower respiratory tract infections, urinary tract infections (UTIs), and acute sinusitis.

- Levofloxacin injection is indicated for the treatment of adults with infections caused by susceptible isolates of the designated microorganisms in the following conditions: nosocomial pneumonia, community-acquired pneumonia, complicated and uncomplicated skin and skin structure infections, chronic bacterial prostatitis, inhalational anthrax (post-exposure), plague, complicated and uncomplicated UTIs, acute pyelonephritis, acute bacterial exacerbation of chronic bronchitis, and acute bacterial sinusitis.

- Metronidazole injection is indicated for the treatment of the following serious infections caused by susceptible anaerobic bacteria: intra-abdominal infections, skin and skin structure infections, gynecologic infections, bacterial septicemia, bone and joint infections, central nervous system infections, lower respiratory tract infections, endocarditis, and as prophylactic therapy to reduce the incidence of postoperative infection in patients undergoing elective colorectal surgery.

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- To date, Claris has not received adverse event reports related to this recall.
- Healthcare providers, distributors and wholesalers should immediately check inventory, quarantine, and discontinue distribution of the recalled product.
- Consumers in possession of the recalled product should stop using the product immediately.
- For questions regarding this recall, contact Claris at **1-877-725-2747**.

Action Plan

- Clinical Services will conduct mailings to member(s) that may be affected by the Claris injectable drugs recall, and to providers who prescribed for the recalled drugs recently.
- Information regarding the Claris recall will be posted on the optumrx.com portals.