

Baxter - Recall of fluconazole and milrinone injection

- On May 22, 2017, <u>Baxter announced</u> a voluntary, consumer-level recall of some lots of <u>fluconazole</u> and <u>milrinone</u> injections due to a potential material defect at the port seal which may lead to leaks in bags.
- The recalled lots were distributed from 11/13/2015 through 4/27/2017.

Product Description	NDC #	Lot # (Expiration date)
Fluconazole injection, in INTRAVIA plastic container, 200 mg/100 mL	0338-6046-48	P352377 (8/31/18), P348136 (4/30/18)
Milrinone lactate 5% in dextrose injection, 20 mg/100 mL (200 mcg/mL), 100 mL, INTRAVIA container	0338-6010-48	P342485(11/30/17), P344408(12/31/17)

- Fluconazole injection is indicated for the treatment of oropharyngeal and esophageal candidiasis
 and cryptococcal meningitis. It is also indicated to decrease the incidence of candidiasis in patients
 undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation
 therapy.
- Milrinone is indicated for the short-term intravenous treatment of patients with acute decompensated heart failure.
- A leak of the fluconazole or milrinone solution bag may allow for delay or interruption of therapy, under-delivery, unintended drug exposure, and microbial contamination. If not detected, the use of a fluconazole or milrinone solution bag with a leak could lead to a bloodstream infection or other serious adverse health consequences.
- To date, Baxter has not received any reports of adverse events related to this recall.
- Anyone with an existing inventory of the recalled product(s) should stop use and distribution, and
 quarantine the product immediately. Patients should contact their healthcare provider if they have
 experienced any problems that may be related to using the recalled product(s).



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