

*The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.*

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a recall of lot WB00006 (Expiry: December 2026) of Ganirelix Acetate Injection 250 mcg/0.5mL (1s Pack) at the retail level. This recall is being conducted due to an out of specification (OOS) result observed in the impurity test (specifically for Ganirelix acetate acrylic acid adduct impurity) during long term stability testing.

Based on toxicological profile and literature search, Ganirelix acetate acrylic acid adduct impurity is considered non-mutagenic and non-carcinogenic. While this impurity's OOS result is unlikely to pose a health hazard, its effect on Ganirelix acetate injection's efficacy in fertility treatment cannot be ruled out.

The recalled lot was distributed nationwide to wholesalers, independent pharmacy and supermarket between March 2025 and July 2025.

PRODUCT: Ganirelix Acetate Injection 250 mcg/0.5mL (1s Pack)

NDC NUMBER: 70748-274-01

LOT NUMBER: WB00006

EXPIRY: 12/2026

DESCRIPTION: Clear, colorless solution free from visible particulate matter filled in prefilled syringe.