

*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.*

Ferring Pharmaceuticals would like to inform you of a product recall for ENDOMETRIN (progesterone) Vaginal Insert, 100 mg, seven (7) blister strips with three (3) tablets each contained in sealed foil pouches. This action follows detection of Burkholderia bacteria in four (4) unreleased lots of ENDOMETRIN during final, routine quality control (QC). These lots were not released to the market. Burkholderia was not detected in any of the recalled lots. However, as a precautionary measure, Ferring has initiated a voluntary Class II (retail level) recall of all lots produced since January 2023. A Health Hazard Evaluation has been prepared by Ferring. Limited available information indicates that the presence of some Burkholderia species may be associated with a risk of maternal colonization/infection, which in turn could potentially impact implantation of the embryo or pregnancy loss. Of note, this limited information points to a potential association, however, no direct causation has been established. Further, these potential risks are also generally associated with infertility and Assisted Reproductive Technology (ART) treatment.

Product: ENDOMETRIN (progesterone) Vaginal Insert, 100 mg

NDC: 55566-6500-3

Lots: AA200A, AA201A

Expiration Date: December 2025