

# ISMP Canada Safety Bulletin Supplement

Volume 26 • Issue 2 • Supplement 1 • February 26, 2026

## Sharing Matters! Concerned Reporting Results in Improved Labelling to Reduce the Risk of Wrong-Route Errors

Boric acid vaginal products are available without a prescription to manage vaginal infections. MedError.ca (ISMP Canada’s consumer reporting program) received a report from a patient who almost ingested a boric acid vaginal suppository (Figure 1), mistaking it for an oral capsule. They shared their experience and provided suggestions to prevent a similar error. The following factors contributed to this near-miss event:

- use of a gelatin capsule that would typically be used for oral medications, vitamins, and supplements
- absence of a vaginal applicator (because an applicator can act as a cue to the route of administration)
- insufficient prominence of the route-of-administration labelling on the principal display panels



**FIGURE 1.** Original labelling and packaging for Utiva boric acid vaginal suppository product.

### MANUFACTURER RESPONSE

ISMP Canada shared this incident with Health Canada and the manufacturer, Szio+ Inc. Following discussions, the manufacturer has added clearer warnings to the outer box, bottle, and product insert. These include a red bar on the outer box and insert stating “FOR VAGINAL USE ONLY. NOT FOR ORAL USE,” as well as a bottle cap safety seal that reads “DO NOT EAT” (Figure 2).



**FIGURE 2.** Improved labelling and packaging for Utiva boric acid vaginal suppository product.

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## RECOMMENDATIONS FOR MANUFACTURERS OF SUPPOSITORIES INTENDED FOR VAGINAL ADMINISTRATION

To reduce the risk of similar incidents, manufacturers are encouraged to do the following:

- Design vaginal suppository products in traditional suppository shapes (e.g., torpedo or cone-shaped) to distinguish them from oral medications.
- Display route-of-administration warnings prominently on the principal display panels of the outer box and the bottle (e.g., “For vaginal use only”).
- Include the formulation (e.g., vaginal suppository) directly under the ingredient name and strength on the principal display panels.
- Include a vaginal applicator with the product to support the correct route of administration.
- Add warnings on labelling and packaging with directions for the consumer if a suppository is mistakenly swallowed.
- Consult Health Canada’s [Good Label and Package Practices Guide for Non-prescription Drugs and Natural Health Products](#) when developing product labelling and packaging.

*ISMP Canada is grateful to the consumer who submitted this report and greatly appreciates the commitment to patient safety demonstrated by Szio+ Inc.*