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ISMP Canada Safety Bulletin Supplement

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Accurate Dosing of Misoprostol for Induction of Labour

ISMP Canada was made aware of the death of a newborn that occurred during induction of labour. One of the recommendations arising from a review undertaken by a provincial death investigation service was the following: "The Society of Obstetricians and Gynaecologists of Canada (SOGC) and ISMP Canada should work together to provide guidance on the use and accurate dosing of misoprostol."

Following this death investigation, the SOGC published updated guidance for cervical ripening and induction of labour, including the preparation and use of misoprostol.[1] For induction of labour, the recommended starting oral dose of misoprostol is 20 to 25 mcg, titrated to effect, to a maximum dose of 50 mcg.[1] Commercially available tablet strengths are 100 mcg and 200 mcg; therefore, tablet manipulation is required to prepare and administer the recommended doses. SOGC suggests preparing a misoprostol solution by dissolving a tablet in water and then administering partial volumes to deliver the prescribed doses.[1]

Health care providers have described challenges with the preparation of misoprostol, either when using partial tablets or preparing a solution. Concerns are related to safe handling*, stability, and the potential for dosing errors.

To support doses recommended by the SOGC and avoid the need to prepare doses at the bedside, misoprostol may be provided by pharmacies in the form of 10 mcg or 25 mcg ready-to-use doses.[3] Options include the following:

- procuring compounded 10 mcg or 25 mcg capsules prepared in a controlled environment and providing the doses in unit dose packaging (Figure 1)
- quartering 100 mcg tablets in a controlled environment, and providing the doses in 25 mcg unit dose packaging

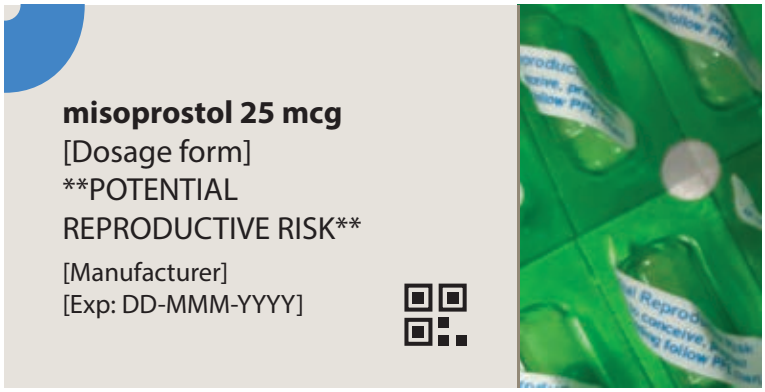

FIGURE 1.
Example of unit dose packaging for misoprostol 25 mcg.

Ideally, misoprostol would be available commercially in doses needed to support safe induction of labour. In the interim, providing obstetrical teams with ready-to-use doses of misoprostol enhances safety by eliminating the need for medication manipulation at the bedside and allowing for more direct patient care time.

* Misoprostol is considered a hazardous drug by the National Institute for Occupational Safety and Health (NIOSH) and may present an occupational hazard to any workers who are actively trying to conceive, are pregnant or may become pregnant, or are breastfeeding (the latter because the drug may be excreted in breast milk).[2]

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Sharon Dore RN PhD, Associate Clinical Professor, Department of Obstetrics and Gynecology, McMaster University, Hamilton, ON; Sebastian R Hobson MD PhD MPH FRANZCOG FACOG FRCSC, Maternal Fetal Medicine Specialist, Head of Labour & Delivery, Mount Sinai Hospital, Chair, Clinical Obstetrics Committee, Society of Obstetricians & Gynaecologists of Canada, Toronto, ON; Brandi Newby RPh BScPharm ACPR, Pharmacy Coordinator, Neonatal and Pediatric Pharmacy, Surrey Memorial Hospital, Surrey, BC; debbie Robinson MD FRCSC CCPE MBA, Medical Director, Obstetrics and Gynecology, St. Boniface Hospital, Winnipeg, MB; Hilary Rowe BScPharm PharmD ACPR, Clinical Pharmacy Specialist – Perinatal Ambulatory Care Consultant, Fraser Health, Surrey, BC.

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3. Personal communication with Benjamin Tanguay PharmD MBA, Pharmacist – Development & Hospital Affairs. Saint-Hyacinthe (QC): Gentès & Bolduc Pharmacists.