

ISMP Canada Safety Bulletin

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ALERT: Multipronged Strategy Required to Manage Shortage of Sterile Water for Injection

On March 17, 2022, the shortage of small-volume formats of sterile water for injection packaged in vials and ampoules was assigned a Tier 3 designation by a Tier Assignment Committee that includes Health Canada and other Canadian stakeholders.¹ Tier 3 shortages are those that have the “greatest potential impact on Canada's drug supply and health care system.”¹ The global shortage is expected to persist into May 2022.²

Small-volume formats of sterile water for injection are widely used for reconstitution of injectable medications.³ Bacteriostatic water for injection and sterile water for irrigation are not considered replacement options for sterile water for injection.⁴ Providing 1-litre bags of sterile water for injection to nursing units for use as a source of diluent is unsafe because repeated manipulation and needle use introduce opportunities for contamination. Such large volumes are specifically intended for use only in the pharmacy, under controlled conditions. Incidents have been previously reported in which large-volume bags of sterile water for injection were inadvertently infused intravenously, causing hemolysis and renal complications.^{5,6}

RECOMMENDATIONS

Managing the shortage of small-volume formats of sterile water for injection requires a multipronged

approach: 1) conservation strategies to maintain existing supply,⁷ 2) implementation of alternative drug preparation processes, and 3) effective communication among all staff affected by the shortage.

The central pharmacy in each health care organization has a key role in assessing and implementing these strategies to maintain safe practices.

1) *Conservation Strategies to Maintain Existing Supply*

- Review the use of vials and ampoules of sterile water for injection to ensure that remaining supplies are reserved for the reconstitution of medications for which this product is required.⁴
 - Assess which medications can be reconstituted with an alternative sterile liquid for injection, and provide clear, product-specific communication to end-users.
- Source premixed products, where available.

2) *Implementation of Alternative Drug Preparation Processes*

- Specify the alternative diluent on the label (or as an auxiliary label) when dispensing medications for which an alternative sterile liquid for injection can be used for reconstitution.

- Explore the capacity of the central pharmacy to dispense medications reconstituted using the large-volume formats of sterile water for injection that continue to be available.
 - Recognize that although this step may ease the situation for front-line staff, staffing and resources in the pharmacy must be considered, both to address the additional workload that this will entail and to meet standards set out by the National Association of Pharmacy Regulatory Authorities.⁸

3) *Effective Communication among All Staff Affected by the Shortage*

- Ensure that communications about this shortage reach all staff affected by the shortage.
- Discuss and confirm with affected departments the potential changes to daily practice, drug distribution, and product alternatives, to strengthen communication.

Information about additional measures to address the shortage have been published by the following organizations:

ISMP (US):³

<https://www.ismp.org/resources/management-drug-shortages-09-sodium-chloride-sterile-water-injection-and-epinephrine>

American Society of Health-System Pharmacists:⁴

<https://www.ashp.org/-/media/assets/drug-shortages/docs/drug-shortages-sterile-water-faq.pdf>

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