





Temporary Product Change

Propofol 10 mg/mL (1%) X 100 mL vials

The Issue: Due to unprecedented demand for propofol across Canada throughout the waves of the COVID-19 pandemic, Health Canada previously approved the importation of US-labelled propofol 10 mg/mL X 100 mL vials from Sagent Pharmaceuticals (Omega) as a national safety stock. Now that propofol demand has decreased, the provinces have been given a supply of these vials to use before they expire on December 31, 2022. Northern Health has received several months worth of stock of this product which will soon be available for use in relevant patient care areas.

Practice Implications:

- Clinicians should be aware of this temporary product change for the remainder of 2022.
- Staff may see both the Canadian-labelled and US-labelled products available as product transition occurs.
- The ready-to-use format, concentration, vial size, and storage is the same between the Canadian-labelled and US-labelled products, and both are for single-use only.
- The US-labelled product does not have a Drug Identification Number (DIN) on the vial and does not contain any information in French.
- KEY PRODUCT DIFFERENCES:
 - The US-labelled product contains a preservative, sodium metabisulfite. Preservatives have <u>rarely</u> been associated with allergic reactions. Clinicians should monitor for signs and symptoms of allergic reaction when administering the US-labelled product.
 - If dilution is required, the US-labelled product should <u>only be mixed with dextrose 5%</u>. The NH Parenteral Drug Administration <u>monograph</u> has been updated on OurNH to include this info.

Product Comparison:

Current Product (Baxter; Canadian-labelled) propofol injection 10 mg/mL (1%) X 100 mL	Temporary New Product (Sagent; US-labelled) propofol injection 10 mg/mL (1%) X 100 mL			
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Preservative-free	Preservative: sodium metabisulfite			
Hangers: pre-attached	Hangers: peel out of the vial label			
Note: propofol is a high risk/high alert medication requiring an independent double check				

February 11, 2022 For the information of	Drug Shortage		For further information contact:
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