





Hydralazine 20 mg/mL X 1 mL Vials

The Issue: Due to the shortage of Canadian-labelled hydralazine 20 mg/mL X 1 mL vials from SteriMax, Health Canada has authorized the importation of a US-labelled product. NH pharmacy will soon have supply of this US-labelled product available for use in NH facilities.

Practice Implications:

- Clinicians should be aware of this temporary product change.
- Staff may see both the Canadian-labelled and US-labelled products as this transition occurs.
- The 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.
- **PRODUCT DIFFERENCES:**
 - **The US-labelled product contains preservatives, methylparaben and propylparaben. Preservatives have rarely been associated with allergic reactions.** Clinicians should monitor for signs and symptoms of allergic reaction when administering the US-labelled product.
 - The US-labelled product specifies FOR IM or IV USE on the label; **however, in Canada, hydralazine injection is authorized for IV administration only.** This is reflected on the NH Parenteral Drug Administration Manual [monograph](#).
 - The US-labelled product can be used in the same manner as the Canadian marketed product. Clinicians should refer to the [Canadian Product Monograph](#) available on Drug Product Database.

Product Comparison:

Current Product (SteriMax; Canadian-labelled) hydralazine 20 mg/mL X 1 mL vial	Temporary New Product (American Regent; US-labelled) hydralazine 20 mg/mL X 1 mL vial
	
Concentration: 20 mg/mL	Concentration: 20 mg/mL
Preservative-free	Preservatives: methylparaben and propylparaben

February 11, 2022 For the information of physicians, nurses, and pharmacists. PLEASE POST	Drug Shortage		For further information contact: Medication Use Management Pharmacists mumpharmacist@northernhealth.ca
	Drug Discontinuation		
	Temporary Product Change	✓	
	Best Practice		