

STERIMAX

2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

Tel.: 905-890-0636 / 800-881-3550 • Fax: 905-890-0508 / 877-546-7667 • Web: www.sterimaxinc.com

Importation of US-labelled Hydralazine Hydrochloride Injection, USP due to shortage of Canadian-labelled Hydralazine Hydrochloride Injection

Date: Monday, January 3, 2022

Audience

Group purchasing organizations (GPOs), healthcare professionals (physicians, surgeons, critical care and emergency room physicians, nurses and pharmacists), and sterile compounding pharmacies.

Key messages

- There is a shortage of Hydralazine Hydrochloride Injection (20 mg/mL) in Canada. To help mitigate the current shortage, Health Canada has not objected to the temporary importation and distribution of limited quantities of American Regent's US-labelled Hydralazine Hydrochloride Injection, USP by SteriMax Inc.
- In Canada, Hydralazine Hydrochloride Injection is indicated for the emergency treatment of severe essential hypertension when the drug cannot be given orally or when there is an urgent need to lower blood pressure (e.g. toxemia of pregnancy or pre-eclampsia).
- The US-labelled product has the **same concentration (i.e. 20 mg/mL) and dosage form** as the Canadian marketed product, but the two products **differ with respect to the non-medicinal ingredients and administration.**
- **The US-labelled product contains the preservatives, methylparaben and propylparaben**, which are absent from the Canadian marketed product.
- The US-labelled product is labelled for intravenous or intramuscular routes of administration; however, **in Canada, Hydralazine Hydrochloride Injection is authorized for intravenous administration only.** Other differences in the administration instructions between the two products are considered minor.
- **The US-labelled product can be used in the same manner as the Canadian marketed product. Healthcare professionals should refer to the Canadian Product Monograph for the marketed Hydralazine**

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Hydrochloride Injection product (20 mg/mL) available on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on proper use including the route of administration, indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

Imported product

Product Name	Hydralazine Hydrochloride Injection, USP
Strength and Fill Size	20 mg hydralazine hydrochloride per mL in water for injection. Available in 1 mL single-use clear glass vials
Foreign Identifying Code and Pack Size	NDC# 0517-0901-25, 25 vials per carton pack
US Market Authorization Holder	American Regent, Inc., 5 Ramsey Road, Shirley, NY, 11967-4701, United States.
Importer/Distributor in Canada	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4

Information for healthcare professionals

Differences in the non-medicinal ingredients and administration between the US-labelled Hydralazine Hydrochloride Injection, USP and the Canadian marketed Hydralazine Hydrochloride Injection can be found in Table 1 below in **bolded** text.

Table 1: Comparison between the US-labelled Hydralazine Hydrochloride Injection, USP and the Canadian marketed Hydralazine Hydrochloride Injection		
Information	US-labelled Hydralazine Hydrochloride Injection, USP	Canadian marketed Hydralazine Hydrochloride Injection
Formulation	Each mL contains: <ul style="list-style-type: none"> Hydralazine Hydrochloride 20 mg Propylene Glycol 103.6 mg Methylparaben 0.65 mg Propylparaben 0.35 mg Water for Injection q.s. pH of solution is 3.4 – 4.4. pH may be adjusted with Hydrochloric Acid and/or Sodium Hydroxide 	Each vial (1 mL) contains: <ul style="list-style-type: none"> Hydralazine Hydrochloride 20 mg Propylene Glycol 103.6 mg Water for Injection q.s. Sodium Hydroxide and Hydrochloric Acid for pH adjustment
Preservative	Methylparaben and Propylparaben	No preservative

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Route of Administration	Intramuscular or Intravenous	Intravenous
Administration Instructions	Instructions are not present in the package insert	For ease of administration the solution may be further diluted with physiological saline.

The US-labelled product can be used in the same manner as the Canadian marketed product. Healthcare professionals should refer to the Canadian Product Monograph for the marketed Hydralazine Hydrochloride Injection product (20 mg/mL) available on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) for information on proper use including the route of administration, indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

The vial and carton labels of the US-labelled product are labelled in English only. Images of the US-labelled product, including the vial and carton labels, can be found below in Annex 1.

Information about the US-labelled Hydralazine Hydrochloride Injection, USP for healthcare professionals is available for reference in English only at the following link: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=17210abc-58f6-442e-8ff2-7971333c82f6>.

The US-labelled product does not have a Drug Identification Number or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow proper identification of the product being dispensed and administered. Proper selection of the intended product must be confirmed to avoid confusion with other products and prevent medication errors.

Report health or safety concerns

Adverse drug reactions associated with the use of Hydralazine Hydrochloride Injection, USP should be reported to SteriMax Inc. by calling 1-800-881-3550 or via email to pv@sterimaxinc.com or to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Original signed by:

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Ritesh Acharya

Ritesh Acharya, M. Pharm.

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SteriMax Inc., Oakville, ON.

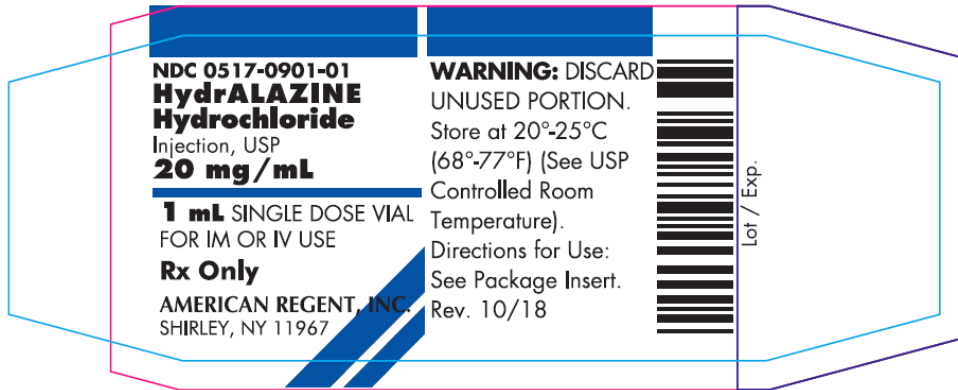
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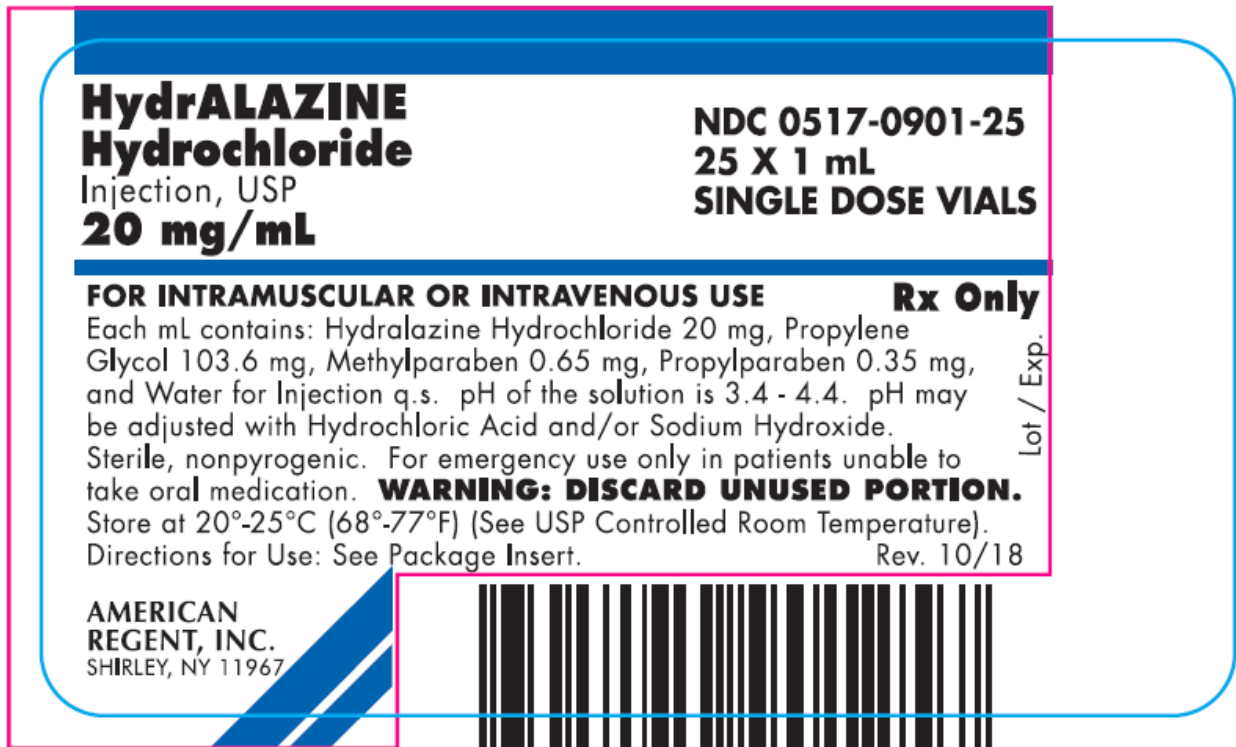
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Annex 1 - Images of American Regent's US-labelled Hydralazine Hydrochloride Injection, USP (20 mg/mL):

Vial Label:



Carton Label:



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Vial Image:



Carton Image:

