

Importation of US-labelled Prazosin Hydrochloride Capsules, USP due to the current shortage of Canadian-authorized Prazosin Hydrochloride Tablets

Date: 11 September 2023

Dear Healthcare professionals (physicians, nurses, pharmacists), wholesalers, HealthPro and Medbuy GPO members.

There is a critical shortage of prazosin hydrochloride tablets in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Alembic's US-labelled Prazosin Hydrochloride Capsules, USP with English only labels, by SteriMax Inc., Oakville, ON.

Health Canada has accepted the addition of Prazosin Hydrochloride Capsules, USP (1 mg, 2 mg, and 5 mg) to the [List of drugs for exceptional importation and sale \(https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html).

In Canada, prazosin hydrochloride tablets (1 mg, 2 mg, and 5 mg) is a prescription drug product indicated in the treatment of hypertension. It has mild to moderate antihypertensive activity. Prazosin is employed in a general treatment program in conjunction with other antihypertensive agents and/or diuretic drugs, depending on the needs of the patient. In cases of mild hypertension, prazosin hydrochloride tablets can be employed as the initial treatment if the physician feels that treatment should be initiated with a sympatholytic rather than a diuretic agent.

The US-labelled product has the **same active ingredient, strengths (1 mg, 2 mg, and 5 mg) and route of administration (oral) as the Canadian marketed products**. The US-labelled product, however, differs in the following ways:

- The **US-labelled product is available as capsules** while the Canadian marketed products are available as tablets. **The US 1 mg capsule cannot be split into a 0.5 mg starting or titration dose.**
- The US-labelled capsules have a **different product composition** (non-medicinal ingredients) than the Canadian marketed products.

Healthcare professionals are advised of the following:

- **With the exception of dosing recommendations using split tablets, the US-labelled product can be used in the same manner as the Canadian marketed products.** As mentioned above, the **US-labelled capsules cannot be split.**
- **Healthcare professionals should refer to the Canadian Product Monographs for prazosin hydrochloride tablets (1 mg, 2 mg, and 5 mg) available in English and French on the Health Canada [Drug Product Database \(https://health-products.canada.ca/dpd-bdpp/\)](https://health-products.canada.ca/dpd-bdpp/).** The Canadian Product Monographs in the database contain information on the appropriate use of the product, including the indications,

STERIMAX

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

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contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

- Consistent with the dosing instructions in the Canadian Product Monographs for prazosin hydrochloride tablets, **the maximum daily dose should not exceed 20 mg for the US-labelled product.**
- **When switching from the Canadian marketed products to the US-labelled product, healthcare professionals are advised to closely monitor patients for blood pressure and safety events (e.g. dizziness, drowsiness, and syncope).**
- Healthcare professionals responsible for dispensing of the US-labelled products are advised to counsel patients that the US-labelled product is in a different oral dosage form (i.e., capsules) but contains the same active ingredient as the Canadian marketed products.

Information on the imported product

| Brand name | Dosage form, strength and route of administration | Product description and packaging | Country of authorization and identifying code | Authorization holder | DEL holder/ Importer in Canada |
|--------------------------------------|---|---|---|--|---|
| Prazosin Hydrochloride Capsules, USP | Capsules Contains prazosin hydrochloride equivalent to 1 mg, 2 mg, and 5 mg of prazosin Oral administration | 1 mg capsules: Opaque white cap/ opaque white body 2 mg capsules: Opaque pink cap/ opaque white body 5 mg capsules: Opaque blue cap/ opaque white body Available in bottle of 100 capsules | United States 1 mg: NDC 62332-691-31 2 mg: NDC 62332-692-31 5 mg: NDC 62332-693-31 | Alembic Pharmaceuticals Limited Bedminster, NJ 07921, USA | SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4 |

Information about US-labelled Prazosin Hydrochloride Capsules, USP for healthcare professionals is available for reference in the English US Prescribing Information at

<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=d4af73d1-c97e-4418-9e24-007b10af0bd9&type=display>.

Refer to Appendix – 01 for product and bottle images of US-labelled Prazosin Hydrochloride capsules, USP.

Refer to Appendix – 02 for the bottle label artwork for US-labelled Prazosin Hydrochloride capsules, USP.

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Healthcare professionals are advised that aspects of the product labels and packaging of the US-labelled product may differ from the Canadian marketed prazosin hydrochloride products. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

The US-labelled product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of US-labelled Prazosin Hydrochloride Capsules should be reported to SteriMax Inc. or to [Health Canada](#).

SteriMax Inc.,
2770, Portland Drive, Oakville, ON, L6H 6R4
Phone: +1-800-881-3550
Fax: +1-877-546-7667
E-mail: pv@sterimaxinc.com

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on [Adverse Reaction Reporting](#) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax.

Questions or concerns

For questions or concerns about US-labelled Prazosin Hydrochloride capsules, please contact SteriMax Inc. at medinfo@sterimaxinc.com OR visit [SteriMax website](#) (<https://sterimaxinc.com/contact-us>).

Appendices:

Appendix 01 – Product and bottle images of US-labelled Prazosin Hydrochloride capsules, USP.


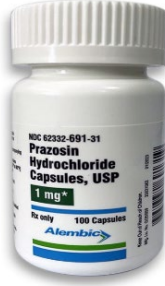




Appendix 02 – Image of the US outer bottle labels:

- NDC 62332-691-31: Prazosin Hydrochloride Capsules, USP, 1 mg.
- NDC 62332-692-31: Prazosin Hydrochloride Capsules, USP, 2 mg.
- NDC 62332-693-31: Prazosin Hydrochloride Capsules, USP, 5 mg.

Original signed by

Ritesh Acharya, M. Pharm.
Executive Vice President, Scientific Affairs
SteriMax Inc., Oakville, ON

Appendix 01 – Product and bottle images of US-labelled Prazosin Hydrochloride capsules, USP:

| Product description | Product image | Bottle image |
|---|---|---|
| <p>NDC 62332-691-31: Prazosin Hydrochloride Capsules, USP, 1 mg.</p> <p>Opaque White Cap/Opaque White Body Hard Gelatin Capsules Size “4”: “A” imprinted on cap in black ink; “320” imprinted on body in black ink; Filled with white to off-white granular powder.</p> |  |  |
| <p>NDC 62332-692-31: Prazosin Hydrochloride Capsules, USP, 2 mg.</p> <p>Opaque Pink Cap/Opaque White Body Hard Gelatin Capsules Size “2”: “A” imprinted on cap in black ink; “321” on body in black ink; Filled with white to off-white granular powder.</p> |  |  |
| <p>NDC 62332-693-31: Prazosin Hydrochloride Capsules, USP, 5 mg.</p> <p>Opaque Blue Cap/Opaque White Body Hard Gelatin Capsules Size ‘0’: “A” imprinted on cap in black ink; “322” imprinted on body in black ink; Filled with white to off-white granular powder.</p> |  |  |

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Appendix 02 – Image of the US outer bottle labels:

- NDC 62332-691-31: Prazosin Hydrochloride Capsules, USP, 1 mg.

***Each capsule contains prazosin hydrochloride, USP equivalent to 1 mg of prazosin.**
DOSAGE AND USE: See accompanying prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Dispense in a tight, light-resistant containers (USP).
Package is Child-Resistant.

Manufactured by:
Alembic Pharmaceuticals Limited
(Formulation Division),
Panelav 389350, Gujarat, India

Manufactured for:
Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, USA

NDC 62332-691-31
Prazosin Hydrochloride Capsules, USP
1 mg*
Rx only 100 Capsules
Alembic

Keep Out of Reach of Children.
Mfg. Lic. No. G/25/959 20031062 01/2023

3 N 9
6 2 3 3 2 - 6 9 1 - 3 1
GTIN: 00362332691319
S.NO./EXP./LOT

Coding Area
NOT TO BE
PRINTED
28x40 mm

- NDC 62332-692-31: Prazosin Hydrochloride Capsules, USP, 2 mg.

***Each capsule contains prazosin hydrochloride, USP equivalent to 2 mg of prazosin.**
DOSAGE AND USE: See accompanying prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Dispense in a tight, light-resistant containers (USP).
Package is Child-Resistant.

Manufactured by:
Alembic Pharmaceuticals Limited
(Formulation Division),
Panelav 389350, Gujarat, India

Manufactured for:
Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, USA

NDC 62332-692-31
Prazosin Hydrochloride Capsules, USP
2 mg*
Rx only 100 Capsules
Alembic

Keep Out of Reach of Children.
Mfg. Lic. No. G/25/959 20031065 01/2023

3 N 6
6 2 3 3 2 - 6 9 2 - 3 1
GTIN: 00362332692316
S.NO./EXP./LOT

Coding Area
NOT TO BE
PRINTED
30x45 mm

- NDC 62332-693-31: Prazosin Hydrochloride Capsules, USP, 5 mg.

***Each capsule contains prazosin hydrochloride, USP equivalent to 5 mg of prazosin.**
DOSAGE AND USE: See accompanying prescribing information.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Dispense in a tight, light-resistant containers (USP).
Package is Child-Resistant.

Manufactured by:
Alembic Pharmaceuticals Limited
(Formulation Division),
Panelav 389350, Gujarat, India

Manufactured for:
Alembic Pharmaceuticals, Inc.
Bedminster, NJ 07921, USA

NDC 62332-693-31
Prazosin Hydrochloride Capsules, USP
5 mg*
Rx only 100 Capsules

Alembic

Keep Out of Reach of Children.
Mfg. Lic. No. G/25/959 2003/1068 01/2/023



N 3
3 62332-693-31
GTIN: 00362332693313
S.NO./EXP/LOT

Coding Area
NOT TO BE
PRINTED
16x50 mm