

## Importation of US-labelled Calcitriol Injection, USP due to the current shortage of Canadian-authorized Calcitriol Injection, USP

SteriMax Inc.  
2770 Portland Drive  
Oakville, ON, Canada L6H 6R4

Date: July 03, 2024

Dear Healthcare professionals (physicians, nurses, pharmacists), wholesalers, and Group Purchasing Organization members.

There is a critical shortage of Calcitriol Injection, USP in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of US-labelled Calcitriol Injection USP, with English only labels, by SteriMax Inc., Oakville, ON.

Health Canada has accepted the addition of the US-labelled Calcitriol Injection, USP product 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, Calcitriol Injection, USP is indicated for the management of hypocalcemia in patients undergoing chronic renal dialysis. It has been also shown to significantly reduce elevated parathyroid hormone levels (PTH) in many of these patients. Reduction of PTH has been shown to result in an improvement in renal osteodystrophy.

The US-labelled product has the **same active ingredient, strength (calcitriol 1 mcg per mL), dosage form (solution) and route of administration (intravenous)** as the Canadian marketed product.

The US-labelled product has a **different product composition (non-medicinal ingredients)** than the Canadian marketed product. **The US-labelled product contains butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA) as antioxidants while the Canadian marketed product has sodium ascorbate as an antioxidant.** Other non-medicinal ingredients remain the same.

The US-labelled product also has a **different packaging format**. The **US-labelled product is available as 1 mL solution in single use amber glass vials sealed with rubber stoppers** while the Canadian marketed product is available as 1 mL solution in single use amber glass ampoules.

Healthcare professionals are advised of the following:

- **The US-labelled product can be used in the same manner as the Canadian marketed product.**
- **For proper use of the product, healthcare professionals should refer to the Canadian Product Monograph for Calcitriol Injection, USP (1 mg/mL) available in English and French on the Health**

Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=88422>).

- The Canadian Product Monograph in the database contains information on the appropriate use of the product, including the:
  - indications
  - contraindications
  - warnings and precautions
  - adverse reactions
  - dosage and administration
  - handling instructions
  - storage conditions

### 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
Calcitriol Injection, USP	Solution (sterile), Calcitriol 1 mcg/mL  For intravenous use only.	Clear, colorless to yellow solution  Each 2 mL single use amber glass vial contains 1 mL of solution.  Available in cartons of 10 vials.	United States  NDC 72266-251-10	Fosun Pharma USA Inc. Princeton, NJ 08540.	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4

Information about the US-labelled Calcitriol Injection, USP for healthcare professionals is available for reference in English at <https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=fe7ea4da-bda0-bb00-e053-6394a90a94e7>.

Refer to the Appendix for vial label, carton label and images of US-labelled Calcitriol Injection USP, 1 mcg/mL, 1 mL vials.

Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the US-labelled product may differ from the marketed Calcitriol Injection, USP product in Canada. **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 Calcitriol Injection, USP should be reported to SteriMax Inc. or to [Health Canada](#). Refer to below for contact information.

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

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

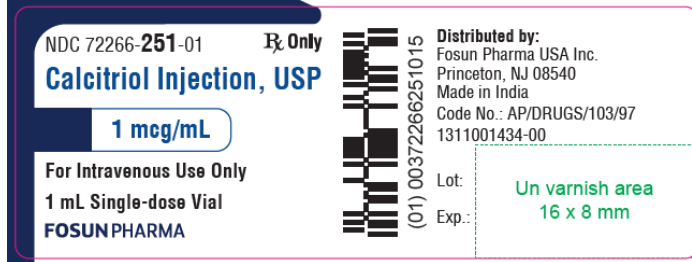
- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect™ Canada's Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>)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

### **Questions or concerns**

For questions or concerns about US-labelled Calcitriol Injection, USP, please contact SteriMax Inc. at [medinfo@sterimaxinc.com](mailto:medinfo@sterimaxinc.com) OR by phone at +1-800-881-3550 / +1-289-218-8682.

## Appendix: Vial label, carton label and images of US-labelled Calcitriol Injection USP, 1 mcg/mL, 1 mL vials

### US Vial Label:



NDC 72266-251-01 **Rx Only**

**Calcitriol Injection, USP**

**1 mcg/mL**

For Intravenous Use Only  
1 mL Single-dose Vial  
FOSUN PHARMA

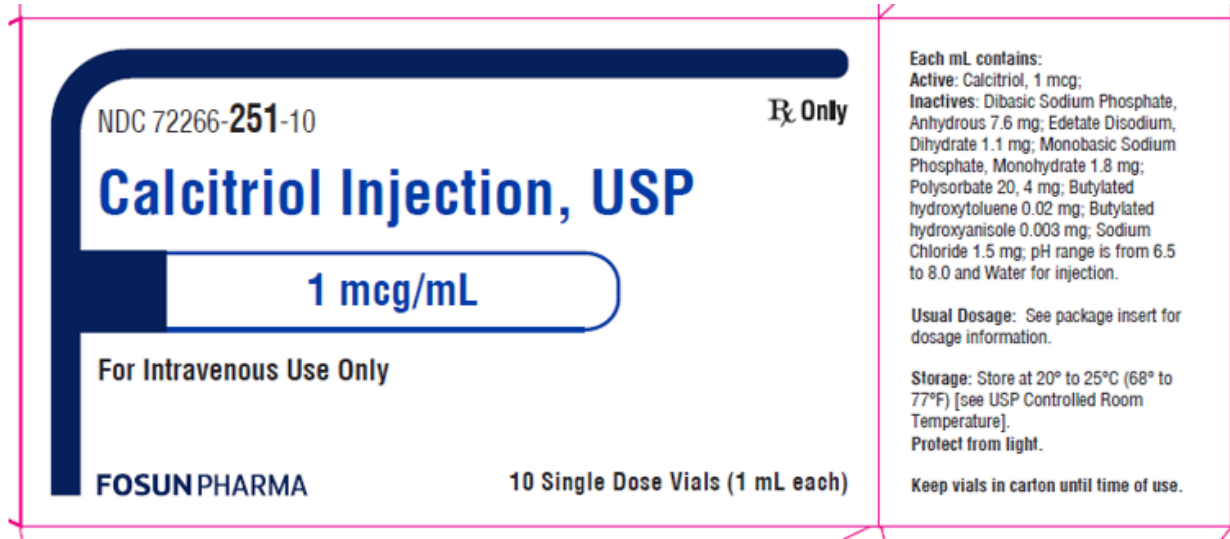
**Distributed by:**  
Fosun Pharma USA Inc.  
Princeton, NJ 08540  
Made in India  
Code No.: AP/DRUGS/103/97  
1311001434-00

Lot:  
Exp.: **Un varnish area  
16 x 8 mm**

(01) 003722662510 15

### US Carton Label:

(Front and Right side panel)



NDC 72266-251-10 **Rx Only**

**Calcitriol Injection, USP**

**1 mcg/mL**

For Intravenous Use Only

FOSUN PHARMA

10 Single Dose Vials (1 mL each)


**Each mL contains:**  
**Active:** Calcitriol, 1 mcg;  
**Inactives:** Dibasic Sodium Phosphate, Anhydrous 7.6 mg; Edetate Disodium, Dihydrate 1.1 mg; Monobasic Sodium Phosphate, Monohydrate 1.8 mg; Polysorbate 20, 4 mg; Butylated hydroxytoluene 0.02 mg; Butylated hydroxyanisole 0.003 mg; Sodium Chloride 1.5 mg; pH range is from 6.5 to 8.0 and Water for injection.

**Usual Dosage:** See package insert for dosage information.

**Storage:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].  
**Protect from light.**

Keep vials in carton until time of use.

(Back and Left side panel)



NDC 72266-251-10 **Rx Only**

**Calcitriol Injection, USP**

**1 mcg/mL**

For Intravenous Use Only

FOSUN PHARMA

10 Single Dose Vials (1 mL each)

**Distributed by:**  
Fosun Pharma USA Inc.  
Princeton, NJ 08540  
Made in India

Code No.: AP/DRUGS/103/97



N  
3 7 2 2 6 6 2 5 1 1 0 1 7

US Product images:

Calcitriol Injection, USP vial:



Calcitriol Injection, USP carton:

