



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

Tel.: 905-890-0661 800-881-3550 • Fax: 905-890-0508 877-546-7667 • Web: www.sterimaxinc.com

Customer Communication

Calcium Chloride Injection BP, 100 mg per mL, 10 mL Pre-Filled Syringe, DIN 02495945

Effective Date: July 25, 2022

Dear Customer:

SteriMax Inc. is providing this important Customer Communication for the following lots of Calcium Chloride Injection BP, 100 mg/mL, 10 mL Pre-Filled Syringe (PFS), DIN 02495945. This communication has been initiated because the affected lots may appear to be blocked or it may seem difficult to dispense the product solution from the syringe.

The following lots are affected (see table below).

Product Name & Strength	DIN	UPC Code	Lot #	Expiry
Calcium Chloride Injection BP, 100 mg/mL, 10 mL PFS	02495945	<i>Outer box: 834324002750</i>	0134670	Jan 2024
		<i>Syringe: (01)00834324002750</i>	0134671	Jan 2024

Note: complaints have been received for the lots listed above, however it is possible this issue can occur with future lots due to its nature.

Information for healthcare professionals:

- Calcium Chloride Injection BP is a single-use pre-filled syringe containing a sterile, ready to use solution. For complete prescribing information, including Dosage and Administration, please refer to the Calcium Chloride Injection BP Canadian Prescribing Information (CPI).
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use unless the solution is clear and the container or seal is intact. Discard if the solution contains a precipitate.

Administration of Calcium Chloride Injection BP

- To administer the medication, the rigid plastic tip cap must be removed and the Calcium Chloride Injection BP product must be connected to a *compatible device*.
 - *If an incompatible device is used, you may experience difficulty connecting to the Calcium Chloride Injection BP PFS. In some cases, connection with an incompatible device may cause a piece of the device to break off in the syringe tip and render the product unusable (due to a blockage).*
- Care should be taken during connection to ensure the luer lock does not come off from the syringe tip, as it is a multi-part device.
- A list of devices that are compatible with the Calcium Chloride Injection PFS is provided with this letter.
- In addition, in order to start movement of the plunger rod and dispensing of the medication, moderate force is needed to overcome the initial resistance (in place to maintain integrity and sterility of the product). However, once this initial resistance is overcome the medication should flow freely using a *compatible connection device*.
- Healthcare professionals are requested to inspect the product before connection to a *compatible device* and post-connection for blockages. Any syringe with a suspected blockage should not be used, segregated, and returned to Sterimax as per the attached Response Form.

STERIMAX

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Report health or safety concerns

Any serious or unexpected side effects experienced by patients receiving Calcium Chloride Injection BP should be reported to SteriMax Inc. or Health Canada.

SteriMax Inc.

E-mail: pv@sterimaxinc.com

Telephone: 1-800-881-3550

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](#) for information on how to report online, by mail or by fax.

For other health product inquiries related to the product and any questions concerning this communication, contact SteriMax at 1-800-881-3550 or email medinfo@sterimaxinc.com.

Thank You,

DocuSigned by:
Mike Riley
7336B683D662457...

Jul 25, 2022

Mike Riley,

Director, Quality Risk Management & Investigations

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Health Professional Response Form

Please complete this form and return to medinfo@sterimaxinc.com for product syringes that appear to be blocked.

Name of Health Professional: _____

Address: _____

City: _____ Province: _____ Postal Code: _____

Phone Number: _____

Email: _____

Complete below table for syringes that appear to be blocked. SteriMax will provide reimbursement to the reporting site.

Product Name & Strength	DIN	UPC Code	Lot #	Expiry	Number of PFS found with blocked tip
Calcium Chloride Injection BP, 100 mg/mL, 10 mL PFS	02495945	<i>Outer box: 834324002750</i> <i>Syringe:</i> <i>(01)00834324002750</i>			

Shipping address for reimbursement product:

Attention to: _____

Address with Postal code _____