

Exceptional Importation of Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion in 10 mL Ampoules Due to the Current Shortage of Canadian-authorized Calcium Chloride Injection

Juno Pharmaceuticals Corp.
402-2233 Argentia Road,
Mississauga, Ontario, Canada
L5N 2X7

March 1, 2024

Dear hospitals, wholesalers, pharmacists and healthcare professional associations:

There is a shortage of Calcium Chloride Injection (100 mg/mL) in Canada.

In order to help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion, with English and Greek labels, by Juno Pharmaceuticals Corp., and has added this 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>).

The Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion is available in 10 mL ampoules and contains 100 mg/mL calcium chloride, and water. Typically for Canadian generic product the manufacturer's name is at the beginning of the brand name, however in this instance "DEMO" is positioned in the middle. This product has also been approved for marketing in the UK by the Medicines & Healthcare products Regulatory Agency (MHRA).

In Canada, Calcium Chloride Injection (100 mg/mL) is indicated to treat low calcium levels in the blood, to treat magnesium intoxication due to overdosage of magnesium sulfate, to treat high potassium levels in blood, and as part of the resuscitation procedure following a cardiac arrest.

The Greece-authorized product and the Canadian-marketed products have the **same active ingredient, strength (100 mg/mL), and route of administration (intravenous or intraventricular cavity injection)**. The non-medicinal ingredients are the same (water) with the exception that the Greece-authorized product does not use sodium hydroxide or hydrochloric acid as a pH adjuster.

The Greece-authorized product is packaged in a single use 10 mL polypropylene ampoule. Special consideration will need to be taken to ensure the appropriate syringes and needles are used. Other products available on the Canadian market are either available in 10 mL pre-filled syringes, or in 10 or 50 mL glass vials.

The Greece-authorized product is labelled as 10% w/v calcium chloride at a concentration of 1.36 mEq/mL, which is equivalent to the Canadian-marketed product which is labelled as 100 mg/mL calcium chloride, or as total strength in mg per total volume. These are two different expressions of strength which both indicate the identical concentration of active ingredient per mL.

There are differences in the approved indications and route of administration among Canadian-marketed Calcium Chloride Injection (100 mg/mL) products.

For proper use of the Greece-authorized product, **healthcare professionals should refer to the Canadian Prescribing Information for marketed Calcium Chloride Injection USP (100 mg/mL) from Pfizer Canada ULC** for information on the indications (including cardiac resuscitation), contraindications, warnings and precautions, adverse reactions, dosing and administration, route of administration (including injection into the ventricular cavity) and storage conditions, available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=4230>).

Please refer to the accompanying package insert and carton labels for the Greece-authorized product for its stability information, such as the expiry date, and directions on using the product's ampoule format.

Information on the imported product

Brand name	Dosage form, strength and route of administration	Product packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Calcium Chloride / DEMO 10% w/v Solution for Infusion	Solution, 100 mg/mL calcium chloride for intravenous or intraventricular cavity injection	10 mL clear polypropylene ampoule. Available in carton packs of 50 ampoules.	Greece 24623/15/2-8-2016	Demo S.A. Pharmaceutical Industry, Greece	Juno Pharmaceuticals Corp., Canada

Information about the Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion for healthcare professionals is available from the MHRA at the following link:

<https://products.mhra.gov.uk/product/?product=CALCIUM%20CHLORIDE%2010%25%20W%2FV%20SOLUTION%20FOR%20INFUSION>

Images of the Greece-authorized product can be found in the Appendix below. Healthcare professionals are advised that other aspects of the inner and outer labels and packaging of the Greece-authorized drug product may differ from marketed Calcium Chloride Injection (100 mg/mL)

products in Canada. **Proper selection of the intended drug product must be verified to avoid confusion with other drug products and prevent medication errors.**

The Greece-authorized 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 Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion should be reported to Juno Pharmaceuticals Corp. by calling 1-855-819-0505 or 1-866-663-1747 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.

Questions or concerns

For questions or concerns about Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion, please contact Juno Pharmaceuticals Corp., 402-2233 Argentia Road, Mississauga, ON, L5N 2X7.

Appendix

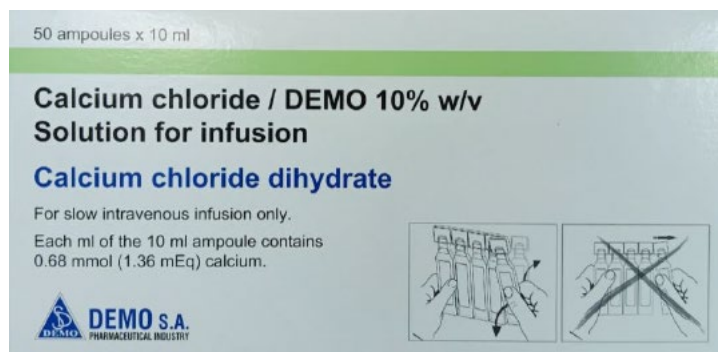
1. Images of Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion

Sincerely,

Paul J. Varady
VP, Quality and Regulatory Affairs
Juno Pharmaceuticals Canada

Appendix - Images of Greece-authorized Calcium Chloride / DEMO 10% w/v Solution for Infusion

Product Photos




Greece Vial Label

<p>Calcium chloride / DEMO 10% w/v 10 ml</p> <p>Solution for infusion Για αργή IV έγχυση μόνο:</p> <p>1 ml περιέχει 0,1 g of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ που αντιστοιχεί περίπου σε 0,68 mmol (1,36 mEq) Ca^{+2} και 1,36 mmol (1,36 mEq) Cl^-.</p>	38011310-4
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Plain text Greece vial label

Main Panel
<p>Calcium chloride / DEMO 10% w/v</p> <p>10 mL</p> <p>Solution for infusion</p> <p>1 ml, 0.1 g of $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ 0.68 mmol (1.36 mEq) Ca^{+2} and 1.36 mmol (1.36 mEq) Cl^-</p> <p>Equivalent wording in Greek</p>


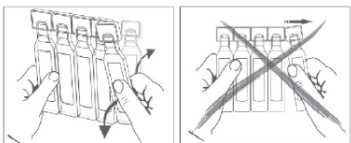

Greece Carton Label – Top Panel

<p>Calcium chloride / DEMO 10% w/v Solution for infusion</p> <p>Calcium chloride dihydrate</p>	
	

Plain text Greece Carton Label – Top Panel

Top Panel
<p>Calcium chloride / DEMO 10% w/v Solution for infusion</p> <p>Calcium chloride dihydrate</p> <p>DEMO S.A. logo</p>

Greece Carton Label – Main Panel and Side Panel

<p>50 ampoules x 10 ml</p>	
<p>Calcium chloride / DEMO 10% w/v Solution for infusion</p> <p>Calcium chloride dihydrate</p> <p>For slow intravenous infusion only.</p> <p>Each ml of the 10 ml ampoule contains 0.68 mmol (1.36 mEq) calcium.</p> <p></p>	<p></p>
<p>For single use only. Each ampoule contains 1 g of the active substance calcium chloride dihydrate. Each gram of calcium chloride dihydrate represents approximately 6.8 mmol (13.6 mEq) calcium and 13.6 mmol (13.6 mEq) chloride. Water for injections. Read the package leaflet before use. This medicinal product does not require any special storage conditions. The product should be used immediately after opening. Any unused solution should be discarded. Do not use this medicine if you notice turbidity, precipitation or discoloration. Solutions containing visible solid particles must not be used. Keep out of the sight and reach of children. By limited medical prescription: For hospital use only.</p> <p>Reg. No: 24623/15/2-8-2016</p> <p> 214 km National Road Athens-Lamia, 145 68 Kironeri, Attiki, Greece T: +30 210 8161802, F: +30 210 8161587</p>	

Plain text Greece carton label Main Panel and Side Panel

Main Panel
<p>50 ampoules x 10 ml</p> <p>Calcium chloride / DEMO 10% w/v Solution for infusion</p> <p>Calcium chloride dihydrate</p> <p>For slow intravenous infusion only.</p> <p>Each ml of the 10 ml ampoule contains 0.68 mmol (1.36 mEq) calcium.</p> <p>DEMO S.A Logo</p> <p>Diagram of how to properly break off ampoules</p>
Side Panel
<p>For single use only.</p> <p>Each ampoule contains 1 g of the active substance calcium chloride dihydrate.</p> <p>Each gram of calcium chloride dihydrate represents approximately 6.8 mmol (13.6 mEq) calcium and 13.6 mmol (13.6 mEq) chloride.</p> <p>Water for Injections.</p> <p>Read the package leaflet before use.</p>

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Solutions containing visible solid particles must not be used.
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By limited medical prescription: For hospital use only.
Reg. No: 24623/15/2-8-2016
DEMO S.A. Logo
21st km National Road Athens-Lamia
145 68 Krioneri, Attiki, Greece
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