



ALCAINE™ (Proparacaine Hydrochloride Ophthalmic solution, USP) 0.5% 15 mL

Product Availability Notice

Alcon Canada Inc.
2665 Meadowpine Blvd.
Mississauga, ON L5N 8C7

10 March 2025

Dear Health Care Practitioner and/or Hospital Purchasing department,

This letter is an update following the original communication provided in **January 2025**.

In the previous letter, Alcon outlines anticipated supply disruptions to the following procedural eye drop product:

Product ID	Product Description	Legacy Material Code
100000045	ALCAINE 0.5% 15ML-CDN	1600

Due to raw material shortage of the Active Pharmaceutical Ingredient (API) used to manufacture this product, we shared that Alcon would experience supply disruptions of ALCAINE™ (Proparacaine Hydrochloride Ophthalmic solution, USP) 0.5% 15 mL effective mid to late January 2025 (**Alcon is now on complete backorder for this product**). Supply is expected to resume by late May 2025, although this is subject to change and dependent on material availability.

However, we are exploring all alternatives and are committed to minimizing the disruption to patients and health care facilities in any way that we can. Alcon has worked with our global supply chain to secure stock of USA labelled ALCAINE™ product, which Health Canada has granted permission for Alcon to import and distribute during the Canadian ALCAINE™ shortage. Please see the second part of the letter, drafted by Alcon's Director of Quality & Regulatory Affairs, which outlines the details of this US-alternative.

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After reviewing the information in the second part of this letter, you should have the information necessary to decide whether or not to accept this alternative version. Your written consent will be required in order for our Customer Service team to substitute this version when you order the original product. Consent will only be required once: once it has been provided, Alcon will continue to automatically fulfill **all orders from your account** with the alternative version until supply of the original version stabilizes.

If you choose to receive the US version, you may notice some differences in product codes / descriptions (which can be found in the table below).

Product ID	Product Description	Legacy Material Code
100064269	ALCAINE 0.5% 15ML SN 288	0000160001

It is important to note that while this stock will help minimize the disruption until supply recovers, it will **not** offset the entire shortage. There will still be periodic disruptions throughout March, until supply starts to stabilize in late-March / April. Please consider ordering only what you need for the next 1-2 months so that we can ensure adequate coverage for patients across Canada. It is likely that some orders will only be partially fulfilled at this time, with the balance shipped 1-2 months later.

Until then, we recommend the following:

- Conduct an inventory of all ALCAINE™ (Proparacaine Hydrochloride Ophthalmic solution, USP) 0.5% 15 mL at your center and note expiry dates
- Ensure use of earliest expiring product first and conservative use of remaining inventory
- Contact wholesalers to see what their supply is like, as there may be available stock that Alcon and your facility do not have visibility into



Questions or concerns

Should you have any questions, please contact your Alcon sales professional or Alcon customer service.

Customer Service contact information:

- **Phone:** 1-800-268-4574
- **Email (for customers who are East of Ontario):** customerservice.canada.east@alcon.com
- **Email (for customers who are in Ontario):** customerservice.canada.central@alcon.com
- **Email (for customers who are West of Ontario):** customerservice.canada.west@alcon.com

Sincerely,

Craig Rosenstein,
Product / Brand Manager, Surgical Consumables
Alcon Canada Inc.
craig.rosenstein@alcon.com



**Importation of USA-labelled ALCaine™ (Proparacaine Hydrochloride Ophthalmic Solution, USP),
0.5% w/v due to the current shortage of Canadian-authorized ALCaine™**

Alcon Canada Inc.
2665 Meadowpine Blvd.
Mississauga, ON L5N 8C7

10 March 2025

Dear Health Care Practitioners,

There is a current critical shortage of ALCaine™ (Proparacaine Hydrochloride Ophthalmic Solution, USP), 0.5% w/v in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of USA-labelled ALCaine™, 0.5% w/v, with English-only labels, by Alcon Canada Inc.

Health Canada has accepted the addition of Alcon Laboratories, Inc.'s USA-labelled ALCaine™ (Proparacaine Hydrochloride Ophthalmic Solution, USP), 0.5% w/v 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, ALCaine™, 0.5% w/v, is indicated for use as a topical anesthetic:

- for ophthalmic procedures such as measurement of intraocular pressure (tonometry), removal of foreign bodies and sutures from cornea, conjunctive scraping in diagnosis and gonioscopic examination
- prior to surgical operations such as cataract extraction.

The USA-labelled product has the **same active ingredient (proparacaine hydrochloride), strength (0.5% w/v), dosage form (solution), route of administration (ophthalmic), volume (15 mL DROP-TAINER™ dispensers), and product formulation** as the Canadian-authorized product. However, the products **differ with respect to dosage and administration, contraindications, and information on pediatric use.**



Health care professionals are advised of the following:

- **The USA-labelled ALCAINE™ should be used in the same manner as the Canadian-authorized product.**
- **To ensure safe and effective use of the product, please consult the Canadian Product Monograph for ALCAINE™ available in English and French on the Health Canada [Drug Product Database \(https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html).**
- The Canadian Product Monograph on the database contains information on the appropriate use of the product, including the indications, warnings and precautions, adverse reactions
- **Please follow the specific detailed information from the Canadian Product Monograph below related to:**
 - **Dosage and administration:**
 - *Deep anesthesia as in cataract extraction: Instill 1 drop every 5 to 10 minutes for 5 to 7 doses.*
 - *Removal of sutures: Instill 1 or 2 drops 2 or 3 minutes before removal of stitches.*
 - *Removal of foreign bodies: Instill 1 or 2 drops prior to operating.*
 - *Tonometry: Instill 1 or 2 drops immediately before measurement.*
 - **Storage conditions:**
 - Store at 2°C - 8°C. Keep refrigerated. Do not use if the solution is darker than a pale yellow.
 - **Contraindications:**
 - **ALCAINE™ is contraindicated and should never be prescribed for the patient's own use.**
 - **Pediatric use:**
 - **ALCAINE™ may be used as a topical ophthalmic anesthetic agent in children when benefit outweighs potential risks.**



Information on the imported product

Brand name	Dosage form, strength and route of administration	Product description, packaging and shelf life	Country of authorization and identifying code	Foreign authorization holder and Manufacturer
ALCAINE™	ALCAINE™ (Proparacaine Hydrochloride Ophthalmic Solution, USP), 0.5% w/v is a topical local anesthetic for ophthalmic use.	<p><u>Product description:</u> Each mL contains : <i>Active:</i> proparacaine hydrochloride 5 mg (0.5% w/v). <i>Preservative:</i> benzalkonium chloride (0.01%). <i>Inactives:</i> glycerin and purified water. The pH (range 4.0 - 6.0) may be adjusted with hydrochloric acid and/or sodium hydroxide.</p> <p><u>Packaging:</u> Supplied in 15 mL DROP-TAINER™ dispensers.</p> <p><u>Shelf-life:</u> 30 months</p>	USA NDC 0998-0016-15	Alcon Laboratories, Inc., USA

Additional information about USA-labelled ALCAINE™ for health care professionals is available for reference in English only at [DailyMed - ALCAINE- proparacaine hydrochloride solution/ drops \(https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0c0fa0bf-977d-4539-b8dc-54c187c5b094\)](https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0c0fa0bf-977d-4539-b8dc-54c187c5b094).

Images of the USA-labelled product can be found in the Appendix. Health care professionals are advised that aspects of the secondary packaging such as inner and outer labels and carton package of the USA-labelled product may differ from the Canadian-authorized product. **Proper selection of the intended**



product must be verified to avoid confusion with other products and prevent medication errors.

The USA-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.

The USA-labelled product is labelled in English only. On request, the French-translated text of the US label can be provided. Please contact Alcon customer service at customerservice.canada@alcon.com or at 1-800-268-4574 or Alcon Canada Medical Information at canada.medinfo@alcon.com or at 1-800-613-2245.

To obtain a copy of the Canadian inner and outer labels in English and French, please contact Alcon Canada Medical Information at canada.medinfo@alcon.com or 1-800-613-2245.

Reporting adverse drug reactions

- Adverse drug reactions associated with the use of ALCAINE™ should be reported to Alcon Complaint Intake Team at complaints.canada@alcon.com / phone 1-800-613-2245 or to
- Health Canada by:
 - Calling toll-free at 1-866-234-2345; or
 - Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax.



Questions or concerns

For questions or concerns about USA-labelled ALCAINE™, please contact Alcon Canada Medical Information at canada.medinfo@alcon.com or 1-800-613-2245.

For question or concerns related to delivery and shipment of the products, please contact Alcon customer service at customerservice.canada@alcon.com or at 1-800-268-4574.

Sincerely,

Germaine Gibson
Director of Quality & Regulatory Affairs
Alcon Canada Inc.
Germaine.gibson@alcon.com

Encl:

Appendix: Pages 9-12 (Product Images of the USA-labelled Product)



Appendix: USA-labelled ALCAINETM (Proparacaine Hydrochloride Ophthalmic Solution, USP), 0.5% w/v in 15 mL DROP-TAINER™ dispensers

For identification purposes, please see below product images of the USA-labelled Product. The USA-labelled product is labelled in English only. The French-translated text of the US label will be made available upon request. Please contact Alcon customer service at customerservice.canada@alcon.com or at 1-800-268-4574 or Alcon Canada Medical Information at canada.medinfo@alcon.com or at 1-800-613-2245.


Description	Picture
US Product Label	



US Product in
Primary Packaging
(bottle, tip and
cap)





Description	Picture
<p data-bbox="155 674 594 743">US Product in Secondary Packaging Top and Bottom Face(s)</p> <p data-bbox="155 1144 324 1178">4 Side Face(s)</p>	 <p>The top and bottom faces of the secondary packaging are shown as small black labels with white text and a QR code. The top face label includes the following information: SN: 17545294240951, LOT: 11Y6X, EXP: JAN 2025, and GTIN: 00309980016156. The side faces of the packaging are shown as two vertical rectangular labels. The left side face label includes the Alcon logo, ALCON LABORATORIES, INC., 8001 South Freeway, Fort Worth, Texas 76134 USA, and Printed in USA. The right side face label includes the NDC number 0998-0016-15, the Alcon logo, the product name Alcaine™ (proparacaine hydrochloride ophthalmic solution USP) 0.5%, and the volume 15 mL Sterile.</p>

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