STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4
Tel.: 905-890-0661, 1-800-881-3550 ● Fax: 905-890-0508, 1-877-546-7667 ● Web: www.sterimaxinc.com

Importation of US-labelled Olanzapine for Injection due to the current shortage of Canadian-authorized Olanzapine Tartrate for Injection

Date: 1 August 2025

Dear Healthcare professionals (including physicians, emergency physicians, psychiatrists, nurses and pharmacists)

There is a critical shortage of Olanzapine for Injection in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of American Regent Inc's US-labelled Olanzapine Tartrate for Injection, 10 mg/vial, with English only labels, by SteriMax Inc.

Health Canada has accepted the addition of US-labelled Olanzapine for Injection, with English only labels, to the List of drugs for exceptional importation and sale.

In Canada, Olanzapine Tartrate for Injection, 10 mg/vial is a prescription drug product indicated for the treatment of adults (18 years of age and older) for the rapid control of agitation in patients with schizophrenia and related psychotic disorders, and bipolar mania.

The US-labelled product has the **same active ingredient, strength (10 mg Olanzapine per vial), dosage form (powder for injectable solution), and route of administration (intramuscular injection) as the Canadian-authorized product**.

Healthcare professionals are advised of the following:

- The colour of the flip off cap for the US-labelled product (violet) differs from the Canadian-authorized product (purple).

- **The US-labelled Olanzapine for Injection is used in the same manner as the Canadian-authorized product.**

- Refer to the Canadian Product Monograph for Zyprexa IntraMuscular (Olanzapine Tartrate for Injection), 10 mg/vial (DIN 02247099) available in English and French on the Health Canada Drug Product Database (https://health-products.canada.ca/dpd-bdpp/) for information on the appropriate use of the product, including the indications, contraindications, warnings and precautions, adverse reactions, dosage and administration, and storage conditions.

- Storage condition for Zyprexa Intramuscular (unreconstituted form) is 15-30^{o}C while the US-labelled product has the storage condition of 20-25^{o}C (USP controlled room temperature storage), which differs from the 15-30^{o}C storage condition for Zyprexa Intramuscular (unreconstituted form).

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Additionally, healthcare professionals are reminded that as with all parenteral drug products, reconstituted solutions should be inspected visually for clarity, particulate matter, precipitation, discolouration and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discolouration or leakage should not be used. Discard any unused portion of the reconstituted product.

Information on the imported US-labelled 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
Olanzapine for Injection (10 mg/vial)	Powder for solution (Sterile). Each vial contains: Olanzapine 10 mg. Administration by Intramuscular Injection.	Yellow freeze-dried cake or powder. Available in a clear glass vial (single-use). Available in cartons of 1 vial. Lot / Expiry: 24255N1C0 / 2026-08 Lot / Expiry: 24268N1C0 / 2026-09	United States NDC 0517-0955-01	American Regent, Inc. Shirley, NY 11967	SteriMax Inc., 2770 Portland Drive, Oakville, ON, L6H 6R4

Information about the US-labelled product for healthcare professionals is available for reference in the English US Prescribing Information at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=e9ac2bd3-dbff-4b1a-952f-da3909c6e4ee.

Refer to Appendix 1 for product images of the US-labelled Olanzapine for Injection
Refer to Appendix 2 for inner and outer labels of the US-labelled Olanzapine for Injection

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

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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 Olanzapine for Injection should be reported to SteriMax or to Health Canada.

SteriMax Inc.,
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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 Olanzapine for Injection, please contact the SteriMax medical information team at medinfo@sterimaxinc.com OR visit the SteriMax website (https://sterimaxinc.com/contact-us).

Appendices

Appendix 1 – Product images of the US-labelled Olanzapine for Injection
Appendix 2 – Inner and outer labels of the US-labelled Olanzapine for Injection (NDC 0517-0955-01)

Original signed by

Signed by Ritesh Acharya
Ritesh Acharya | I approve this document
Aug 1, 2025 | 7:20:45 AM EDT
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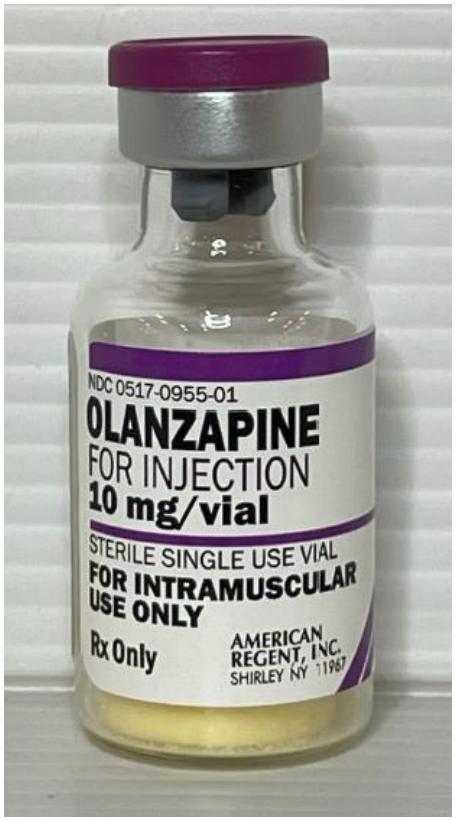
Appendix 1 – Product images of the US-labelled Olanzapine for Injection:

Product description	Vial Image	Carton Image
NDC 0517-0955-01: Olanzapine for Injection, 10 mg/vial Clear glass vial with gray rubber stopper and aluminum seal with violet color flip off cap.		

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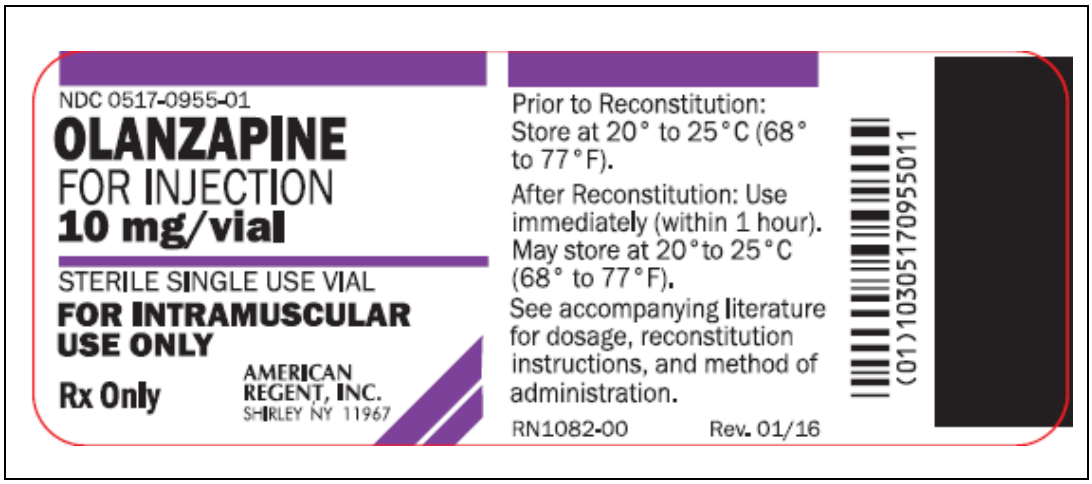
Appendix 2 – Inner and outer labels of the US-labelled Olanzapine for Injection:

NDC 0517-0955-01: Olanzapine for Injection, 10 mg/vial

Inner label (Vial):



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Outer label (Carton):