

April 9, 2024

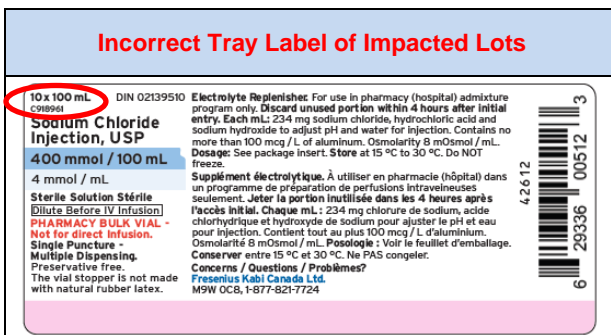
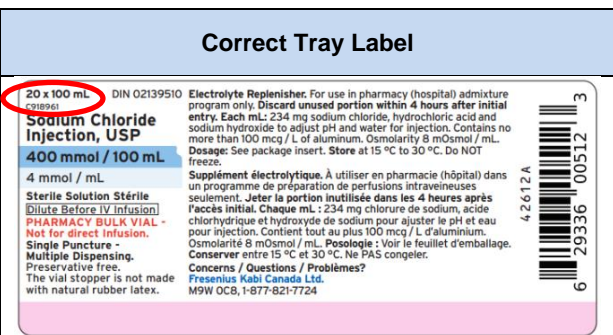
Sodium Chloride Injection, USP 4 mmol/mL PBV 100 mL Labelling Error Notice

Dear Valued Customer,

Fresenius Kabi Canada would like to advise that the following lots of **Sodium Chloride Injection, USP 4 mmol/mL PBV 100 mL** were impacted by a labelling error. The trays containing **20 vials** were incorrectly labelled as containing **10 x 100 mL vials**. Please see the table below for a more detailed look at the labelling discrepancy.

Although this has been classified as a labelling error related to quantity, it does not pose any safety implications for patients. **All lots & orders contain the expected 20 vials/pack**, with no discrepancy in quantity shipped.

DIN	Fresenius Kabi Product Code	MDP Product Code	McKesson Product Code	Description	Impacted Lots
02139510	C918961	977536	179105	Sodium Chloride Injection, USP 4 mmol/mL PBV 100 mL	6029967 exp. 12/2025 6029968 exp. 12/2025 6033136 exp. 08/2026 6034009 exp. 11/2026 6034010 exp. 11/2026 6034011 exp. 11/2026 6034012 exp. 11/2026

Incorrect Tray Label of Impacted Lots	Correct Tray Label
 <p>10 x 100 mL (circled in red) DIN 02139510 c918961 Sodium Chloride Injection, USP 400 mmol / 100 mL 4 mmol / mL Sterile Solution Stérile <u>Billute Before IV Infusion</u> PHARMACY BULK VIAL - Not for direct infusion. Single Puncture - Multiple Dispensing. Preservative free. The vial stopper is not made with natural rubber latex.</p> <p>Electrolyte Replenisher. For use in pharmacy (hospital) admixture program only. Discard unused portion within 4 hours after initial entry. Each mL: 234 mg sodium chloride, hydrochloric acid and sodium hydroxide to adjust pH and water for injection. Contains no more than 100 mcg / L of aluminum. Osmolarity 8 mOsmol / mL. Dosage: See package insert. Store at 15 °C to 30 °C. Do NOT freeze. Supplément électrolytique. À utiliser en pharmacie (hôpital) dans un programme de préparation de perfusions intraveineuses seulement. Jeter la portion inutilisée dans les 4 heures après l'accès initial. Chaque mL : 234 mg chlorure de sodium, acide chlorhydrique et hydroxyde de sodium pour ajuster le pH et eau pour injection. Contient tout au plus 100 mcg / L d'aluminium. Osmolarité 8 mOsmol / mL. Posologie : Voir le feuillet d'emballage. Conserver entre 15 °C et 30 °C. Ne PAS congeler. Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p>	 <p>20 x 100 mL (circled in red) DIN 02139510 c918961 Sodium Chloride Injection, USP 400 mmol / 100 mL 4 mmol / mL Sterile Solution Stérile <u>Billute Before IV Infusion</u> PHARMACY BULK VIAL - Not for direct infusion. Single Puncture - Multiple Dispensing. Preservative free. The vial stopper is not made with natural rubber latex.</p> <p>Electrolyte Replenisher. For use in pharmacy (hospital) admixture program only. Discard unused portion within 4 hours after initial entry. Each mL: 234 mg sodium chloride, hydrochloric acid and sodium hydroxide to adjust pH and water for injection. Contains no more than 100 mcg / L of aluminum. Osmolarity 8 mOsmol / mL. Dosage: See package insert. Store at 15 °C to 30 °C. Do NOT freeze. Supplément électrolytique. À utiliser en pharmacie (hôpital) dans un programme de préparation de perfusions intraveineuses seulement. Jeter la portion inutilisée dans les 4 heures après l'accès initial. Chaque mL : 234 mg chlorure de sodium, acide chlorhydrique et hydroxyde de sodium pour ajuster le pH et eau pour injection. Contient tout au plus 100 mcg / L d'aluminium. Osmolarité 8 mOsmol / mL. Posologie : Voir le feuillet d'emballage. Conserver entre 15 °C et 30 °C. Ne PAS congeler. Concerns / Questions / Problèmes? Fresenius Kabi Canada Ltd. M9W 0C8, 1-877-821-7724</p>

We recognize the inconvenience you may experience as a result of this labelling error, and we thank you for your patience and understanding in this matter. Should you have any questions or concerns, please reach out to our Customer Service Department at (877) 821-7724.

Sincerely,



Joseph Le
Associate Director, IV Drugs
joseph.le@fresenius-kabi.com



Scan and register to receive our communications via email.