

April 12, 2023

Expiration Dating Error on Carton Labels for Lot 6401160 of Dilaudid® (HYDROmorphone Hydrochloride) Injection, USP

To Our Valued Customers,

This letter is to alert you of a **carton label printing defect present on Lot 6401160** of Dilaudid® (HYDROmorphone Hydrochloride) Injection, USP 0.5 mg per 0.5 mL prefilled syringes.

The defect is a mismatch between the expiration date printed on the carton unit and the expiration date printed on the syringe label. The product was manufactured in July 2022 and has an approved shelf life of 36 months. The expiration dating on carton units is incorrectly printed as July 2024. The expiration dating on the syringe labels is correctly printed as July 2025. **Product is within expiry and safe to use.**

Fresenius Kabi notified the FDA of this defect on 3/7/2023. An internal investigation revealed that the printing error occurred during the process of updating the product to the current 36 month shelf life. Corrective and preventative actions (CAPA) have been completed and we have confirmed that no other product lots are affected.

For Wholesalers/Distributors, please communicate this information to all accounts that have been shipped the affected product.

For full Prescribing Information, including BOXED WARNING, for Dilaudid® (HYDROmorphone Hydrochloride) Injection, USP, [please click here](#).

For product availability updates, please visit our web site at www.fresenius-kabi.com/us/pharmaceutical-product-availability, call our Customer Service team at 1-888-386-1300, or contact your wholesaler.

Thank you,



Matt Kozak
 Director, Marketing – Simplist® Prefilled Syringes

Table 1 – Expiration Dating for Lot 6401160

Product	Presentation	Unit of Sale NDC	Unit of Use NDC	Shelf Life	Expiration Date
Dilaudid® (HYDROmorphone Hydrochloride) Injection, USP	0.5 mg per 0.5 mL Prefilled Syringe	76045-009-06	76045-009-96	36 months	July 31, 2025