Click for full <u>Prescribing Information</u> for fluconazole in sodium chloride injection, solution

Pfizer Inc.275 North Field Drive
Lake Forest, IL 60045



February 14, 2025

Notification of Packaging Error: Fluconazole in Sodium Chloride Injection, USP 400 mg/200 mL (2 mg/mL) Flexible Container

Dear Valued Customer,

We want to make you aware of an error on the packaging of our Fluconazole in Sodium Chloride Injection, USP 400 mg/200 mL (2 mg/mL) Flexible Container, NDC 00409-4321-24, impacting lot numbers 54524001, 54524002, 54524003, 54524004, 54524005, 54524006, 54524007, and 54524008. Specifically, the NDC number located on the product's outer carton—or the external cardboard box that contains 24 flexible containers—is incorrect as noted in the table below.

It is important to note that the NDC is accurately encoded on both the flexible container (I.V. plastic bag) and secondary (overwrap) packaging. The only aspect affected is the preprinted NDC on the external carton, which does not impact the overall traceability or identification of the scanned products.

The correct GTINs, which contain the correct NDC information, have been encoded in the GS1 DataMatrix codes (2D barcode) and linear 1D barcodes on all affected packaging, ensuring accurate traceability and compliance with global standards. The GS1 DataMatrix codes on the packaging contain the correct NDC information encoded along with other critical data elements such as Lot Number, Serial Number, and Expiry Date.

Unit of Sale (UoS) NDC	Product Description	Impacted Lots	INCORRECT NDC Currently appears on outer carton	Correct NDC
00409-4321-24	Fluconazole in Sodium Chloride Injection, USP 400 mg/200 mL (2 mg/mL) Flexible Container	54524001 54524002 54524003 54524004 54524005 54524006 54524007 54524008	00409-4321-01	00409-4321-24

Please reference the Full Prescribing Information available <u>here</u>.

No other aspects of the product or package labeling, including the active pharmaceutical ingredient or formulation, have been impacted by this error.

The above-mentioned batches of the finished products remain fully compliant with traceability requirements, and there is no impact on the product's identification and distribution status.

If you have any questions regarding this notification, please contact our Customer Service Department at 1-844-646-4398 or via email at PICustomerServices@pfizer.com.

Thank you,

Roman Savchenko

Portfolio Director, Premix & Pain Pfizer Hospital U.S.

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