

IMPORTANT VACCINE PRESCRIBING INFORMATION CORRECTION
 Fluzone[®], Influenza Virus Vaccine, Single-Dose Vials NDC 49281-011-10

November 14, 2011

Dear Health-care Professional:

We are sending this letter to notify you of an error in the Prescribing Information (PI) that was included in packages of 10 single-dose vials of Fluzone vaccine (National Drug Code [NDC] 49281-011-10).

The third column header (labeled “Fluzone 0.5 mL Dose”) and fourth column header (labeled “Fluzone High-Dose 0.5 mL Dose”) in “Table 8: Fluzone, Fluzone High-Dose, and Fluzone Intradermal Ingredients” were inadvertently transposed, resulting in reversing the listings of ingredients and quantities per 0.5mL dose for Fluzone and Fluzone High-Dose vaccines. The correct version of Table 8 appears below and the full PI is available at www.VaccineShoppe.com. Please note that Fluzone vaccine contains 0.05% gelatin.

Table 8: Fluzone, Fluzone High-Dose, and Fluzone Intradermal Ingredients

Ingredient	Quantity (per dose)			
	Fluzone 0.25 mL Dose	Fluzone 0.5 mL Dose	Fluzone High-Dose 0.5 mL Dose	Fluzone Intradermal 0.1 mL Dose
Active Substance: Split influenza virus, inactivated strains^a:				
A (H1N1)	22.5 mcg HA total	45 mcg HA total	180 mcg HA total	27 mcg HA total
A (H3N2)	7.5 mcg HA	15 mcg HA	60 mcg HA	9 mcg HA
B	7.5 mcg HA	15 mcg HA	60 mcg HA	9 mcg HA
Other:				
Sodium phosphate-buffered isotonic sodium chloride solution	QS ^b to appropriate volume	QS ^b to appropriate volume	QS ^b to appropriate volume	QS ^b to appropriate volume
Formaldehyde	≤50 mcg	≤100 mcg	≤100 mcg	≤20 mcg
Octylphenol Ethoxylate	≤75 mcg	≤150 mcg	≤250 mcg	≤50 mcg
Gelatin	0.05%	0.05%	None	None
Preservative				
Single-Dose Presentations	None	None	None	None
Multi-Dose Presentation (Thimerosal)	N/A	25 mcg mercury	N/A	N/A

^a per United States Public Health Service (USPHS) requirement.

^b Quantity Sufficient.

N/A not applicable

The PI that is the subject of this notification was only included in packages of 10 single-dose vials of Fluzone vaccine and has serial copy number 6044. The serial copy number can be found at the beginning and end of the PI. The PIs packaged with all other Fluzone vaccine presentations are not affected. If you have any packages containing the PI with serial number 6044, please discard the PI and refer to the correct PI, which is available at www.VaccineShoppe.com. The vaccine does not need to be returned and may continue to be administered to patients per the label.

Sanofi Pasteur is committed to supplying our customers with products that are safe and effective, properly labeled, and produced to meet appropriate quality standards. If you have any questions about this notification, please contact us at 1-800-VACCINE (1-800-822-2463).

This voluntary product correction is being conducted with the knowledge of the U.S. Food and Drug Administration.

Please accept our apologies for any inconvenience we may have caused. You are a valued Sanofi Pasteur customer and we greatly appreciate your cooperation in these efforts.

Sincerely,



Michael D. Decker, MD, MPH
Vice President, Scientific & Medical Affairs