

High-Dose Seasonal Flu Vaccine Set for 2010-2011

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FROM MMWR

Physicians have a new option this year for vaccinating patients aged 65 and older against seasonal influenza, but vaccine experts can't say for sure whether it will keep more people from getting the flu, according to findings in the Morbidity and Mortality Weekly Report.

On Dec. 23, 2009, the Food and Drug Administration licensed Sanofi-Pasteur's Fluzone High-Dose vaccine, an injectable inactivated trivalent influenza vaccine that provides four times the amount of antigen contained in standard flu vaccines. The aim is to increase the immune response among older adults, who are at greater risk for hospitalization and death from seasonal influenza. The new vaccine will be available for the first

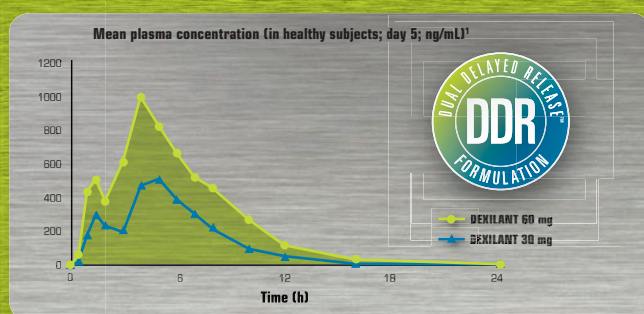
time in the 2010-2011 flu season.

Immunogenicity data from pre-licensure clinical trials showed that people aged 65 and older who received the high-dose vaccine had significantly higher hemagglutination inhibition titers against all three influenza virus strains, compared to the standard-dose Fluzone vaccine. While the higher immune response to vaccination generally correlates with protection against influenza, it

is still unclear whether it will translate into fewer vaccine recipients getting the flu this year, according to the report (MMWR. 2010;59:485-6).

About 36% of 2,572 people who received Fluzone High-Dose reported injection-site pain in the week after receiving the vaccine, compared with 24% of 1,275 who received standard-dose Fluzone. However, the reactions were generally mild and didn't last long. ■

DEXILANT is the first and only PPI with a Dual Delayed Release™ (DDR) formulation, which provides a second release of drug



- DEXILANT 30 mg provided full 24-hour heartburn relief in a majority of symptomatic non-erosive gastroesophageal reflux disease patients at week 4¹

Conclusions of comparative efficacy cannot be drawn from this information.

Indications

DEXILANT is indicated for healing all grades of erosive esophagitis (EE) for up to 8 weeks, maintaining healing of EE for up to 6 months, and treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks.

Important Safety Information

DEXILANT is contraindicated in patients with known hypersensitivity to any component of the formulation. Hypersensitivity and anaphylaxis have been reported with DEXILANT use. Symptomatic response with DEXILANT does not preclude the presence of gastric malignancy. Most commonly reported treatment-emergent adverse reactions: diarrhea (4.8%), abdominal pain (4.0%), nausea (2.9%), upper respiratory tract infection (1.9%), vomiting (1.6%), and flatulence (1.6%). Do not co-administer atazanavir with DEXILANT because atazanavir systemic concentrations may be substantially decreased. DEXILANT may interfere with absorption of drugs for which gastric pH is important for bioavailability (e.g., ampicillin esters, digoxin, iron salts, ketoconazole). Patients taking concomitant warfarin may require monitoring for increases in international normalized ratio (INR) and prothrombin time. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Concomitant tacrolimus use may increase tacrolimus whole blood concentrations.

Please see adjacent brief summary of prescribing information for DEXILANT.

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