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Zoster Live Vaccine (Zostavax®)

DESCRIPTION

Zostavax® is a live, attenuated varicella-zoster virus (VZV) vaccine. It is indicated for the prevention of herpes zoster (shingles) in people 60 years of age and older and is given subcutaneously as a single dose of 0.65 mL.

WHAT THE PHARMACIST SHOULD KNOW

The vaccine should be reconstituted only with the supplied diluent. It must be stored frozen and reconstituted immediately upon removal from the freezer. However, the diluent must be stored at room temperature or in the refrigerator. The appearance of the vaccine will be a semi-hazy to translucent, off-white to pale yellow liquid after reconstitution. It must be administered immediately and should be discarded if not used within 30 minutes. It should not be given to patients with a history of an anaphylactic/anaphylactoid reaction to gelatin, neomycin or other components of the vaccine; history of primary or acquired immunodeficiency states; on immunosuppressive medications; with active untreated tuberculosis or who are or may be pregnant. Zostavax® should not be given to children or used as a substitute for Varivax®.

WHAT YOU MAY NOT BE TOLD

The incidence of herpes zoster is approximately 1 million or more per year in the United States. More than half of the patients who develop herpes zoster are over the age of 60. Complications of the viral infection occur in almost 50 percent of this patient population. The pain and discomfort associated with herpes zoster and post-herpetic neuralgia leads to significant morbidity in the elderly. The risk of developing herpes zoster is associated with an age-

related decrease in VZV-specific immunity. Zostavax® increases VZV immunity and prevents zoster and its complications. In the Shingles Prevention Study, 38,546 subjects who were 60 years or older either received a single dose of Zostavax® or placebo. Eligible subjects had either a history of varicella or had resided in the U.S. for 30 years or more. Over 95 percent of the enrolled subjects completed the study. After a three-year follow-up period, the vaccine was found to have decreased the burden of illness due to herpes zoster by 61.1 percent ($p < 0.001$), the incidence of post-herpetic neuralgia by 66.5 percent ($p < 0.001$) and the incidence of herpes zoster by 51.3 percent ($p < 0.001$). The efficacy of the vaccine was greater in patients 60-69 years old and decreased with increasing patient age. The vaccine also decreased post-herpetic neuralgia in patients 70 years of age and older who developed herpes zoster after being vaccinated.

WHAT THE PATIENT SHOULD KNOW

The duration of protection against herpes zoster is not known. The Shingles Prevention Study showed disease protection for up to four years. Currently, there are no guidelines for revaccination. The clinical trial did not investigate the use of Zostavax® in patients with a history of herpes zoster. The side effects associated with the vaccine included injection-site reaction which was significantly increased in patients who received Zostavax® compared to placebo (48 percent for Zostavax® and 17 percent for placebo). The AWP for a single dose of the vaccine is \$181.69.

RESOURCES

New England Journal of Medicine article:

<http://content.nejm.org/cgi/content/full/352/22/2271>

Zostavax® Package Insert: <http://www.zostavax.com/>

DISCLAIMER

This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.

