



ZOSTAVAX® (Zoster Vaccine Live): IMPORTANT INFORMATION REGARDING STORAGE AND HANDLING

On July 22, 2009, the United States Food and Drug Administration (FDA) approved a change in the Prescribing Information for ZOSTAVAX defining the specific conditions under which ZOSTAVAX could be stored at refrigerator temperature in connection with a change to expiry dating for the product. As a result of this approved change, the *Handling and Storage* subsection of Section 16 of the Prescribing Information, **HOW SUPPLIED/STORAGE AND HANDLING**, was revised as follows (new text is highlighted):

Handling and Storage

During shipment, to ensure that there is no loss of potency, the vaccine must be maintained at a temperature of -15°C ($+5^{\circ}\text{F}$) or colder. **ZOSTAVAX SHOULD BE STORED FROZEN at an average temperature of -15°C ($+5^{\circ}\text{F}$) or colder until it is reconstituted for injection. Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains an average temperature of -15°C or colder is acceptable for storing ZOSTAVAX.**

ZOSTAVAX may be stored and/or transported at refrigerator temperature (2° to 8°C , 36° to 46°F) for up to 72 continuous hours prior to reconstitution. Vaccine stored at 2° to 8°C (36° to 46°F) that is not used within 72 hours of removal from -15°C ($+5^{\circ}\text{F}$) storage should be discarded.

For information regarding stability under conditions other than those recommended, call 1-800-MERCK-90.

Before reconstitution, protect from light.

The diluent should be stored separately at room temperature (20° to 25°C , 68° to 77°F), or in the refrigerator (2° to 8°C , 36° to 46°F).

In accordance with FDA's approval of this change, this highlighted revision to the handling and storage requirements applies only to product with 15-month expiry dating.

During the months of April and May, we are shipping both 15-month expiry dated product and 18-month expiry dated product. Only 15-month expiry dated product may be refrigerated for up to 72 hours as per the Prescribing Information. Product with 18-month expiry dating should NOT be stored or transported at refrigerator temperatures (2° to 8°C , 36° to 46°F) for any period of time.

- **Product with updated 15-month expiry dating will have the following lot numbers printed on the product: 1765Y, 0296Z, 0478Z, and successive lot numbers starting with 0534Z (eg, 0534Z, 0535Z, 0536Z, etc.).**

Prior to storing ZOSTAVAX under the updated storage and handling conditions, please confirm the lot number is consistent with the information provided above. **To ensure that there is no loss of potency, ZOSTAVAX should be stored consistent with the Prescribing Information contained in the packaging shipped with the product.**

For more information, please contact the Merck National Service Center at 1-800-NSC-MERCK (1-800-672-6372) or contact your Merck representative.

About ZOSTAVAX

ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 60 years of age and older.

ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia.

Select Safety Information

Vaccination with ZOSTAVAX may not result in protection of all vaccine recipients.

ZOSTAVAX and PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent) should not be given concurrently because concomitant use resulted in reduced immunogenicity of ZOSTAVAX.

ZOSTAVAX is contraindicated in: persons with a history of anaphylactic or anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; persons with a history of primary or acquired immunodeficiencies; persons on immunosuppressive therapy; pregnant women or women of childbearing age. ZOSTAVAX is not indicated for prevention of primary varicella infection (chickenpox). Transmission of vaccine virus may occur rarely between vaccinees and susceptible contacts.

Serious vaccine-related adverse reactions that have occurred following vaccination with ZOSTAVAX include asthma exacerbation and polymyalgia rheumatica. Other serious adverse events reported following vaccination with ZOSTAVAX include cardiovascular events (congestive heart failure, pulmonary edema). The rate of serious adverse reactions from Days 0 to 42 postvaccination may be increased. Common adverse reactions occurring in $\geq 1\%$ of vaccinated individuals include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.

Click here for the [Prescribing Information for ZOSTAVAX](#)