



## ZOSTAVAX® (Zoster Vaccine Live)

### IMPORTANT INFORMATION REGARDING THE STORAGE AND HANDLING OF ZOSTAVAX

On July 22, 2009, the United States Food and Drug Administration (FDA) approved a change to the Prescribing Information for ZOSTAVAX defining the specific conditions under which ZOSTAVAX could be stored at refrigerator temperature in connection with a change to the 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 in product circular version 9815909 to read 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°F) or colder.

**ZOSTAVAX SHOULD BE STORED FROZEN at an average temperature of -15°C (+5°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°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.

**At this time, Merck has not shipped any product with 15-month expiry dating. All vials of ZOSTAVAX currently in your possession expire on the date indicated on the vial label and should NOT be stored or transported at refrigerator temperature (2° to 8°C, 36° to 46°F) for any period of time.**

To ensure that there is no loss of potency, ZOSTAVAX must be maintained at a temperature of -15°C (+5°F) or colder, consistent with the Prescribing Information contained in the packaging shipped with the vaccine vial.

Merck & Co., Inc., is committed to providing the most up-to-date information possible. For more information, please contact the Merck National Service Center at 1-800-NSC-MERCK (1-800-672-6372).

#### **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 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 ≥1% of vaccinated individuals include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.

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