IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE ZOSTER VACCINE

I. <u>ORDER</u>:

1. Screen for contraindications.
2. Provide the current Shingles Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
4. Reconstitute the vaccine using only the diluent supplied.
   Give Zostavax® vaccine (0.65 ml) subcutaneously, preferably in the upper arm, as a single dose.

Pharmacist signature Date

II. LICENSED LIVE ZOSTER VACCINE

Product Name	Vaccine components	Acceptable Age Range	Preservatives
Zostavax®[1] (Merck)	Oka/Merck strain of live attenuated varicella-zoster virus (VZV)	≥60 years of age	None

[1]Each dose contains approximately 15mg of gelatin with trace quantities of neomycin and bovine calf serum.

Original provided courtesy of the Oregon State Public Health Division
Immunization Program
September 2006

III. INDICATIONS FOR USE:

A. For the prevention of herpes zoster (shingles) in individuals 60 years of age and older.[1,2,3]

[1]Zostavax® is not indicated for the treatment of zoster or postherpetic neuralgia (PHN).
[2]The use of vaccine in individuals with a previous history of zoster has not been studied.
[3]Concurrent administration of Zostavax® and other vaccines has not been evaluated.

IV. VACCINE SCHEDULE FOR ZOSTAVAX®[1,2,3]

Age	Number of Doses	Route	Dosage
≥60 years	**1**	**Subcutaneous injection**	**0.65 ml**

[1]Zostavax® is stored frozen and should be reconstituted immediately upon removal from the freezer. The diluent should be stored separately at room temperature or in the refrigerator.
[2] Vaccine should be administered within 30 minutes of reconstitution, or discarded.
[3] Duration of protection is unknown. Protection has been demonstrated through 4 years of follow-up. The need for revaccination has not been defined.

V. CONTRAINDICATIONS

A. History of anaphylactic reaction to gelatin, neomycin, or other component of the vaccine.
B. History of primary or acquired immunodeficiency states including leukemia: lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic system.
C. On immunosuppressive therapy, including high-dose corticosteroids.[1]
D. With active untreated tuberculosis
E. Who are or may be pregnant[2]

[1] Safety and efficacy have not been evaluated in individuals receiving daily topical or inhaled corticosteroids or low-dose oral corticosteroids.
[2] Pregnancy should be avoided for 3 months following vaccination.

VI. PRECAUTIONS

A. Deferral of vaccination should be considered in acute illness.
B. The risk of transmitting the attenuated vaccine virus to a susceptible individual should be weighed against the risk of developing natural zoster that can be transmitted to a susceptible individual.[3]

[3] In clinical trials with Zostavax®, transmission of the vaccine virus has not been reported.

VII. SIDE EFFECTS AND ADVERSE EVENTS[1,2]

Adverse Experiences	Zostavax® (N= 3345) %	Placebo (N= 3271) %
Injection Site		
Erythema	33.7	6.4
Pain or tenderness	33.4	8.3
Swelling	24.9	4.3
Hematoma	1.4	1.4
Pruritus	6.6	1.0
Warmth	1.5	0.3
Systemic		
Headache	1.4	0.8

[1]Taken from Table 6 (p.7) in Zostavax® package insert issued May 2006
[2]Injection site adverse experiences were solicited only from day 0-4.

VIII. ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.org. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510

IX. REFERENCES

1. Merck & CO., Inc. Zostavax® package insert. Available at www.**merck**.com/product/usa/pi_circulars/z/**zostavax**/**zostavax**_pi.pdf

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, a consulting physician, or contact the Oregon State Public Health Immunization Program at (971) 673-0300.

Electronic copy of this protocol available at:
http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml
To request this material in an alternate format (e.g., braille), please call (971) 673-0300