

IMMUNIZATION PROTOCOL FOR PHARMACISTS

LIVE ZOSTER VACCINE

Revisions as of 8/09

- Persons taking antivirals active against the herpes virus family should discontinue these meds ≥ 24 hours before Zostavax® vaccine administration and not use for ≥ 14 days after vaccination. (Sect. 3, p.2)
- Immunocompetent persons ≥ 60 years of age without a history of zoster vaccination, and anticipating initiation of immunosuppressive treatment, should receive 1 dose of zoster vaccine while their immunity is intact. (Section III, p. 2)
- Contraindication updates regarding vaccinating post leukemia treatment and high dose corticosteroid therapy. (Section V, p.3)
- Other Considerations (Section VIII, p.4) advises how to deal with patients receiving blood products or using low-dose corticosteroids; and administration errors.

I. ORDER:

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.
 - Vaccinate within 30 minutes of reconstitution, or discard.
5. 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	None

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

III. INDICATIONS FOR USE:

A. Adults ≥60 years of age whether or not they report a prior episode of herpes zoster.^{1,2,3}

- Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for this condition.
- Persons taking chronic antiviral medications acyclovir, famciclovir, and valacyclovir should discontinue these medications at least 24 hours before administration of zoster vaccine; these medications should not be used for at least 14 days after vaccination.⁴
- Immunocompetent persons ≥60 years of age, without a history of zoster vaccination and anticipating initiation of immunosuppressive treatment, should receive 1 dose of zoster vaccine while their immunity is intact.

¹Zostavax® is not indicated for the treatment of zoster or post-herpetic neuralgia (PHN).

²Zoster vaccine can be administered with other indicated vaccines during the same visit. (e.g., Td, Tdap, PPV23, and Influenza)

³Although the safety and efficacy of zoster vaccine have not been assessed in persons with a history of zoster, different safety concerns are not expected in this group.

⁴These and any other medications active against members of the herpes virus family might interfere with replication of the live, VZV-based zoster vaccine.

IV. VACCINE SCHEDULE FOR ZOSTAVAX®^{1,2,3}

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

¹Zostavax® 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.
²Vaccine should be administered within 30 minutes of reconstitution, or discarded.
³Duration of protection is unknown. Protection has been demonstrated through 4 years of follow-up. The need for revaccination has not been defined.

V. CONTRAINDICATIONS

VI. PRECAUTIONS

<p>A. History of anaphylactic reaction to gelatin, neomycin, or other components of the vaccine.</p> <p>B. History of primary or acquired immunodeficiency states, including leukemia¹, lymphoma, or other malignant neoplasms affecting the bone marrow or lymphatic system.</p> <p>C. Current immunosuppressive therapy, including high-dose corticosteroids²</p> <p>D. Active untreated tuberculosis</p> <p>E. Pregnancy³</p>	<p>A. Deferral of vaccination should be considered in acute illness.</p> <p>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.⁴</p>
<p>¹With a doctor's order, those whose leukemia is in remission and who have not received chemotherapy or radiation for at least 3 months can receive zoster vaccine.</p> <p>²Zoster vaccine should be deferred for ≥1 month after discontinuation of therapy. Refer to Sect VIII p4 for directions for short-term or low-dose corticosteroid therapy.</p> <p>³Pregnancy should be avoided for 3 months following vaccination.</p>	<p>⁴In clinical trials with Zostavax®, transmission of the vaccine virus has not been reported.</p>

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. OTHER CONSIDERATIONS

- A. Persons receiving blood products:** Zoster vaccine can be administered to persons at any time before, concurrent with, or after receiving blood or other antibody-containing blood product, because persons with a history of varicella indefinitely maintain high levels of antibody to VZV.
- B. History of Varicella vaccine:** While zoster vaccination is not recommended for persons who have received varicella vaccine, virtually all persons currently in the recommended age group have not received vaccination (begun in 1995). Therefore, health care providers do not need to inquire about vaccination history.
- C. Short-term or low dose corticosteroid therapy:** Therapy of <14 days; low-to-moderate dose (<20 mg/day of prednisone or equivalent); topical, nasal, skin, inhaled; intra-articular, bursal or tendon injections; or long-term alternate-day treatment are not considered sufficiently immunosuppressive to cause concerns for vaccine safety. Refer to MMWR 2008; 57(RR-05) for more specific direction:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5705a1.htm>
- D. Administration errors:** If a provider mistakenly administers *varicella* vaccine to persons for whom *zoster* vaccine was intended, no specific safety concerns exist; however, the dose should not be considered valid, and zoster vaccine should be

administered during the same visit or ≥ 28 days after the misadministration.

IX. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the Oregon State Public Health Immunization Program, using a Vaccine Adverse Events Reporting System (VAERS) form, according to state guidelines. Private providers report all adverse events directly to VAERS. VAERS phone number: (800) 822-7967. The website address is: www.vaers.hhs.gov. Administration errors involving zoster vaccine should be reported to VAERS whether or not an adverse event occurs.

X. REFERENCES

1. CDC. Prevention of herpes zoster: recommendation of the Advisory Committee on Immunization Practices (ACIP). MMWR 2008; 57 (RR-05): 1–30. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e0515a1.htm>.
2. 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 your health officer, medical provider, or call the Oregon State Public Health Immunization Program at 971-673-0300.

To download this order visit our website at <http://oregon.gov/dhs/ph/imm/provider/stdgordr.shtml>.
To request this material in an alternate format (e.g., Braille), please call 971-673-0300.