Protocol for Zoster Vaccine
(SHINGRIX®)

1. What's New

A. N/A

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of zoster vaccine to persons ≥19 years of age according to age and high-risk condition.[1]

B. Zoster vaccine can be administered concomitantly, at different anatomic sites, with other adult vaccines.[2]

3. Vaccine Schedule

Shingrix®[1] Dose and Route – 0.5-mL, IM		
Dose	**Acceptable Age range**	**Minimum Acceptable Spacing**
1	≥ 19* years	2 doses at 0 and 2-6 months[+]
2		

*Ages 19-49 for persons with selected immunocompromising conditions including: hematopoietic cell transplant (HCT) recipients, solid organ transplant recipients, patients with cancer, persons living with human immunodeficiency virus (HIV) and patients with autoimmune and inflammatory conditions.[2]

[+]For persons who are or will be immunodeficient or immunosuppressed and who would benefit from completing the series in a shorter period, the second dose can be administered 1–2 months after the first.[2]

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Shingrix®[1]	Varicella zoster virus	0.5-mL single- dose vials packaged with single-dose diluent	≥ 18 years	None

5. Recommendations for Use[1]

A. Recombinant Herpes Zoster Vaccine (RZV) is routinely recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged 50 years and older and does not require pre-screening for chickenpox (varicella).

B. Immunocompromised adults aged 19 years and older should receive a two-dose series of RZV.[2]

C. Persons previously vaccinated with live zoster vaccine (Zostavax) should be revaccinated with RZV. Studies evaluated safety and immunogenicity ≥ 5 years after receipt of live zoster vaccine. Per ACIP, RZV should not be given < 2 months after live zoster vaccine.

D. Persons with a history of herpes zoster should receive RZV. Patients experiencing an episode of zoster should wait to be vaccinated until the acute stage of the illness is over and symptoms have abated.

E. Persons with chronic medical conditions (e.g., diabetes mellitus, chronic renal failure, rheumatoid arthritis, and chronic pulmonary disease) should receive RZV.

F. ACIP recommends using RZV in persons taking low-dose immunosuppressive therapy (e.g., < 20 mg/day of prednisone or using inhaled or topical steroids), persons anticipating immunosuppression or people who have recovered from immunocompromising illness.

G. Persons known to VZV negative should receive varicella vaccine, not RZV. See the varicella immunization protocol for schedule information.

6. Contraindications

A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.[1]

Vaccine	Contains[3]
Shingrix®	Sucrose, sodium chloride, dioleoyl phosphatidylcholine (DOPC), 3-O-desacl4'monophosphoryl lipid A (MPL), QS-21 (a saponin purified from plant extract Quillaja saponaria Molina), potassium dihydrogen phosphate, cholesterol, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, dipotassium phosphate, polysorbate 80, host cell protein and DNA.

7. Warnings and Precautions[1,4]

A. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should not be administered during an acute episode of herpes zoster.
B. In a post marketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following RZV vaccination.

8. Other Considerations

A. Recombinant vaccines such as RZV may be given to breastfeeding women and pose no known risk to the mother or infant.[5]
B. Antiviral therapy, such as acyclovir, may be given concurrently with RZV.
C. The RZV adjuvant solution may contain up to 0.75 mL of liquid. The entire volume of the adjuvant solution should be withdrawn and used to reconstitute the lyophilized RZV vaccine. After mixing, withdraw the recommended dose of 0.5 mL. Any reconstituted vaccine left in the vial should be discarded.
D. The vaccine series does not need to be restarted if more than 6 months have elapsed since the first dose.[4]

9. Side Effects and Adverse Reactions[1]

Adverse Event	Frequency
Any local reaction—pain, redness, induration or swelling at injection site	Very common, up to 78%
Any systemic reaction—fatigue, headache, muscle ache, fever	Very common, up to 45%
Gastrointestinal	Uncommon, up to 17%
Severe (grade 3) systemic reactions—irritability, drowsiness	Uncommon, up to 2% (similar to placebo group)

*At least 17% of recipients will experience an adverse reaction that may disrupt activities of daily living and last up to 3 days.

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10. Storage and Handling[1]

A. Store medications according to OAR 855-041-1036.

Vaccine	Temp	Storage Issues	Notes
Shingrix®	2°to 8°C (36°to 46°F)	Protect vials from light. Do not freeze. Discard if the adjuvant suspension or antigen component has been frozen.	Discard reconstituted vaccine if not used within 6 hours.

11. References

1. Shingrix®. [Package insert]. May 2023. Available at: www.fda.gov/media/108597/download. Accessed 21 July 2023.
2. Centers for Disease Control and Prevention. (2022, January 20). Clinical considerations for use of recombinant zoster vaccine (RZV, Shingrix) in immunocompromised adults aged ≥19 years. https://www.cdc.gov/shingles/vaccination/immunocompromised-adults.html Accessed 21 July 2023
3. Vaccine Excipient Summary. Available at: https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf Accessed 21 July 2023
4. Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. MMWR 2018;67:103–8. Available at: www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6703a5-H.pdf. Accessed 21 July 2023
5. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). ACIP General Best Practice Guidelines for Immunization | CDC Accessed 21 July 2023

12. Appendix

A. N/A