**Recombinant Zoster Vaccine (RZV),SHINGRIX®**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Recommended Schedule:**

Recombinant zoster vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) for these age groups:

* Adults Aged 50 Years and Older
  + **SHINGRIX**® (RZV) vaccine is indicated for prevention of herpes zoster (shingles) and related complications for immunocompetent adults aged 50 years and older.
  + RZV vaccine is recommended (per ACIP) for the prevention of herpes zoster (shingles) and related complications for immunocompetent adults aged 50 years of age and older who previously received zoster vaccine live, ZVL (ZOSTAVAX®). \* RZV vaccine should not be given less than 2 months after receipt of ZVL.
  + RZV vaccine is preferred (per ACIP) over ZVL vaccine for the prevention of herpes zoster and related complications in adults aged 50 years and older.
  + RZV vaccine is recommended (per ACIP) in adults aged 50 years and older with chronic medical conditions (e.g., chronic renal failure, diabetes mellitus, rheumatoid arthritis, and chronic pulmonary disease).
  + RZV vaccine is recommended (per ACIP) in adults aged 50 years and older taking low-dose immunosuppressive therapy (e.g., less than 20 mg/day of prednisone or equivalent or using inhaled or topical steroids) and persons anticipating immunosuppression or who have recovered from an immunocompromising illness.
* Adults Aged 60 Years and Older -administer either RZV or ZVL (RZV is preferred).

**Dosage and Route**

Administer 0.5 mL of reconstituted RZV intramuscularly (IM) (see package insert).

**SHINGRIX**® vaccine is administered as a series of two doses. Administer the first dose at month 0 followed by a second dose administered anytime between 2 and 6 months later.

The vaccine series need not be restarted if more than 6 months have elapsed since the first dose; however, the efficacy of alternative dosing regimens has not been evaluated, data regarding the safety of alternative regimens are limited, and individuals might remain at risk for herpes zoster during a longer than recommended interval between doses 1 and 2. If the second dose of RZV is given less than 4 weeks after the first, the second dose should be repeated. Two doses of the vaccine are necessary regardless of prior history of herpes zoster or prior receipt of ZVL.

**Anatomical Site** - Intramuscular injection in the deltoid region of the upper arm.

**Contraindications**

DO NOT administer **SHINGRIX**® to individuals with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of **SHINGRIX**®. (see package insert 11 DESCRIPTION).

**Warnings and Precautions**

* Preventing and Managing Allergic Vaccine Reactions: Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of **SHINGRIX**®.
* Current herpes zoster infection. RZV is not a treatment for herpes zoster or postherpetic neuralgia and should not be administered during an acute episode of herpes zoster.
* Pregnancy and breastfeeding. There are no available data to establish whether RZV is safe in pregnant or lactating women and there is currently no ACIP recommendation for RZV use in this population. Consider delaying vaccination with RZV in such circumstances
* Moderate or severe illness with or without fever (temporary deferral)

**Adverse Reactions**

* Local adverse reactions in individuals aged 50 years and older were pain (78%), redness (38.1%), and swelling (25.9%)\*
* General adverse reactions in individuals aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%)\*
* \*About 1 out of 6 individuals who got recombinant zoster vaccine experienced side effects that prevented them from doing regular activities. Symptoms went away on their own in about 2 to 3 days. Side effects were more common in younger individuals.
* \*\*To report SUSPECTED ADVERSE REACTIONS, contact VAERS at 1-800-822-7967 or http://[www.vaers.hhs.gov](http://www.vaers.hhs.gov).

**Storage and Handling**

* **SHINGRIX**® is supplied as two components: A single vial of adjuvant suspension component and a single vial of lyophilized gE antigen component.
* Storage before Reconstitution
  + Adjuvant suspension component vials: Store refrigerated between 36oF and 46oF (2oC and 8oC). Protect vials from light. Do not freeze. Discard if the adjuvant suspension has been frozen.
  + Lyophilized gE antigen component vials: Store refrigerated between 36oF and 46oF (2oC and 8oC). Protect vials from light. Do not freeze. Discard if the antigen component has been frozen.
* Storage after Reconstitution: After reconstitution, administer **SHINGRIX**® immediately or store refrigerated between 36oF and 46oF (2oC and 8oC) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours. Do not freeze. Discard if the vaccine has been frozen.
* Prepare **SHINGRIX**® by reconstituting the lyophilized varicella zoster virus glycoprotein E (gE) antigen component with the accompanying AS01B adjuvant suspension component. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid
* To reconstitute the vaccine (See the Package Insert):
  + Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component by slightly tilting the vial (blue-green cap). Vial 1 of 2.
  + Slowly transfer entire contents of syringe into the lyophilized gE antigen component vial (brown cap). Vial 2 of 2.
  + Gently shake the vial to thoroughly mix contents until powder is completely dissolved.
* After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer **intramuscularly**.

**Other Important Notes**

* Immunosuppressive therapies may reduce the effectiveness of **SHINGRIX**®
* Whereas RZV is licensed for all persons aged ≥50 years, immunocompromised persons and those on moderate to high doses of immunosuppressive therapy were excluded from the efficacy studies (ZOE-50 and ZOE-70), and thus, ACIP has not made recommendations regarding the use of RZV in these patients.
* **SHINGRIX**® can be administered concomitantly, at different anatomic sites, with other adult vaccines.
* Adults with a history of herpes zoster (shingles) should receive RZV. If a patient is experiencing an episode of herpes zoster, vaccination should be delayed until the acute stage of the illness is over and symptoms abate.
* Before vaccination, providers should counsel RZV recipients about expected systemic and local reactogenicity.
  + Reactions to the first dose did not strongly predict reactions to the second dose.
  + Vaccine recipients should be encouraged to complete the series even if they experienced a grade 1-3 reaction to the first dose of RZV.
  + \*Grade 3 side effects prevent an individual from doing their regular activities. (See VIS: RZV 2/12/2018
* The vial stoppers are not made with natural rubber latex.

**Resources:**

Dooling KL, Guo A, Patel M, Lee GM, Moore K, Belongia, EA, Harpaz R. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. MMWR Morb Mortal Wkly Rep 2018;67:103–108, <https://www.cdc.gov/mmwr/volumes/67/wr/mm6703a5.htm>

Food and Drug Administration. **SHINGRIX**® (Package Insert). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration: 2017

<https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM581605.pdf>

Vaccine Information Statement (VIS): Recombinant Zoster (Shingles) Vaccine, RZV: *What You Need to Know*; U.S. Department of Health and Human Services (CDC); 2/12/2018

<https://www.cdc.gov/vaccines/hcp/vis/vis-statements/shingles-recombinant.html>

Footnotes to the “Recommended Immunization Schedule for Adults Aged 19 Years or Older, United States, 2018”:

<http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>

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