

SHINGRIX: RECOMMENDED BY THE CDC FOR THE PREVENTION OF SHINGLES*

The CDC states that SHINGRIX is¹:



Recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥ 50 years



Recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL)



Preferred over ZVL for the prevention of herpes zoster and related complications

Please see Important Considerations on opposite side.

For more information on the CDC recommendations for SHINGRIX, visit SHINGRIXHCP.com

*Advisory Committee on Immunization Practices (ACIP) recommendations adopted by the CDC.
CDC=Centers for Disease Control and Prevention.

Indication

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information

- SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
- Review 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
- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%)
- Solicited general adverse reactions in subjects 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%)
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion
- Vaccination with SHINGRIX may not result in protection of all vaccine recipients



SHINGRIX
(ZOSTER VACCINE
RECOMBINANT, ADJUVANTED)

Please see opposite side for Summary of CDC Clinical Guidance.

Please see accompanying full Prescribing Information.

SUMMARY OF CDC CLINICAL GUIDANCE

General Use¹

Recombinant zoster vaccine (RZV) may be used in adults aged ≥ 50 years, irrespective of prior receipt of varicella vaccine or ZVL, and does not require screening for a history of chickenpox (varicella).

ZVL remains a recommended vaccine for prevention of herpes zoster in immunocompetent adults aged ≥ 60 years.² Care should be taken not to confuse ZVL, which is stored in the freezer and administered subcutaneously, with RZV, which is stored in the refrigerator and administered intramuscularly.

Please refer to the Morbidity and Mortality Weekly Report (MMWR) for information on:

- Coadministration with other vaccines
- Counseling for reactogenicity

Immunization Action Coalition (IAC) Recommendations for Local Reactions³

According to the IAC, consider advising patients to apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication post vaccination. These are general recommendations from IAC and have not been evaluated with SHINGRIX.

IMPORTANT CONSIDERATIONS REGARDING THE 2018 CDC RECOMMENDATIONS

Dosing Schedule⁴

The CDC recommendations contain dosing schedule information that is inconsistent with the label for SHINGRIX. According to the Prescribing Information for SHINGRIX, 2 doses (0.5 mL each) should be administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

Concomitant Use^{1,4}

SHINGRIX was administered concomitantly with FLUARIX QUADRIVALENT (Influenza Vaccine) in an open-label clinical study of subjects 50 years and older (N=828). There was no evidence of interference in the immune response to any of the antigens contained in SHINGRIX or the coadministered vaccine. Evaluation of coadministration of SHINGRIX with other vaccines is ongoing.

Patients Previously Receiving Varicella Vaccine

The safety and efficacy of SHINGRIX have not been evaluated in patients that previously received varicella vaccine.

Patients Previously Vaccinated With ZVL

- There are limited data on vaccination with SHINGRIX in patients previously vaccinated with ZVL compared to those not previously vaccinated with ZVL⁵
 - In a phase 3 study, humoral immunogenicity was non-inferior among subjects previously vaccinated at least 5 years earlier with ZVL
 - No apparent safety differences were observed between study groups within 30 days post-dose 2 of SHINGRIX
 - Solicited local and systemic symptoms were similar between study groups
- The levels of antibodies and immune cells that correlate with protection against shingles have not been clearly defined

There are no head-to-head clinical trials comparing the efficacy and safety of SHINGRIX to ZVL

References: **1.** Centers for Disease Control and Prevention. Recommendations of the Advisory Committee on Immunization Practices for use of herpes zoster vaccines. *MMWR*. 2018;67(3):103-108. **2.** Centers for Disease Control and Prevention. Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2008;57(RR-5):1-30. **3.** Immunization Action Coalition. Medical Management of Vaccine Reactions in Adult Patients. <http://www.immunize.org/catg.d/p3082.pdf>. Accessed November 1, 2017. **4.** Prescribing Information for SHINGRIX. **5.** Gruppung K, Campora L, Douha M, et al. Immunogenicity and safety of the HZ/su adjuvanted herpes zoster subunit vaccine in adults previously vaccinated with a live attenuated herpes zoster vaccine. *J Infect Dis*. 2017;216(11):1343-1351.



SHINGRIX
(ZOSTER VACCINE
RECOMBINANT, ADJUVANTED)

Please see Important Safety Information on opposite side and accompanying full Prescribing Information.

All trademarks are the property of their respective owners.



©2018 GSK group of companies or its licensor.
Printed in USA. 832821R0 March 2018