

Important Considerations for the Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines¹

The CDC guidance contains information that is not contained within the label for SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted).

Alternate Dosing

The guidance contains dosing schedule information that is inconsistent with the label. 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.²

Concomitant Use

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.²

Patients Previously Vaccinated With Zoster Vaccine Live (ZVL)

- There are limited data on vaccination with SHINGRIX in patients previously vaccinated with ZVL compared to those not previously vaccinated with ZVL³
 - 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

Persons With a Prior History of Herpes Zoster

The pivotal clinical trials for SHINGRIX excluded patients with a prior history of herpes zoster.²

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

The 2018 CDC Zoster (Shingles) Vaccine Recommendations can be found by visiting:

https://www.cdc.gov/mmwr/volumes/67/wr/mm6703a5.htm?s_cid=mm6703a5_w

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

Please see additional Important Safety Information for SHINGRIX on next page and full Prescribing Information at SHINGRIXHCP.com.

Important Safety Information for SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted) (cont'd)

- In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
- Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
- Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
- Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
- The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
- It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion
- Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see full Prescribing Information at SHINGRIXHCP.com.

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. Prescribing Information for SHINGRIX. 3. Gruppig 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.

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