

## **Important Considerations for the Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines<sup>1</sup>**

**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.<sup>2</sup>

### **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.<sup>2</sup>

### **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 ZVL<sup>3</sup>
  - 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.<sup>2</sup>

### **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](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](http://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 additional Important Safety Information on previous page and full Prescribing Information at [SHINGRIXHCP.com](https://www.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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