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Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022

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Some of the uses of or information about SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted) discussed in the above article are inconsistent with the Prescribing Information for SHINGRIX.

Dosing[1]

This article 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.

For individuals who are or will be immunodeficient or immunosuppressed and who would benefit from a shorter vaccination schedule: A first dose at Month 0 followed by a second dose administered 1 to 2 months later.

Coadministration With Other Vaccines[1]

There has been no systematic evaluation of the coadministration of SHINGRIX with other adult vaccines in immunocompromised patients ≥18 years of age. In an open-label clinical study, subjects aged ≥50 years received 1 dose each of SHINGRIX and FLUARIX QUADRIVALENT (Influenza Vaccine) (QIV) at Month 0 and 1 dose of SHINGRIX at Month 2 (n=413), or 1 dose of QIV at Month 0 and 1 dose of SHINGRIX at Months 2 and 4 (n=415). There was no evidence for interference in the immune response to any of the antigens contained in SHINGRIX or the coadministered vaccine. Evaluation of the coadministration of SHINGRIX with other vaccines is ongoing.

Patients Previously Vaccinated With Zoster Vaccine Live (ZVL)[2-7]

In the clinical trials evaluating the use of SHINGRIX in immunocompromised patients ≥18 years of age, 5 studies excluded those who had been vaccinated with ZVL within the previous 12 months[2-6] and 1 study excluded those who had ever been previously vaccinated with ZVL.[7]

Patients With a Prior History of Herpes Zoster[2-7]

The clinical trials of SHINGRIX in immunocompromised patients ≥18 years of age excluded those with a history of herpes zoster within the previous 12 months.

Breastfeeding Patients[1]

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.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SHINGRIX and any potential adverse effects on the breastfed child from SHINGRIX or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

Indication

SHINGRIX is a vaccine indicated for prevention of herpes zoster (HZ) (shingles):

- in adults aged 50 years and older.
- in adults aged 18 years and older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy.

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 on reverse and accompanying full Prescribing Information for SHINGRIX.

Important Safety Information *(cont'd)*

- In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)
- 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%)
- Solicited local adverse reactions reported in autologous hematopoietic stem cell transplant recipients (aged 18 to 49 and ≥50 years of age) were pain (88% and 83%), redness (30% and 35%), and swelling (21% and 18%)
- Solicited general adverse reactions reported in autologous hematopoietic stem cell transplant recipients (aged 18 to 49 and ≥50 years of age) were fatigue (64% and 54%), myalgia (58% and 52%), headache (44% and 30%), gastrointestinal symptoms (21% and 28%), shivering (31% and 25%), and fever (28% and 18%)
- 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 reverse and accompanying full Prescribing Information for SHINGRIX.

References: 1. Prescribing Information for SHINGRIX. **2.** Data on file. Study 115523 (NCT01610414). GSK Study Register. Study entry at: https://www.gsk-studyregister.com/en/trial-details/?id=115523. **3.** Data on file. Study 116428 (NCT01767467). GSK Study Register. Study entry at: https://www.gsk-studyregister.com/en/trial-details/?id=116428. **4.** Data on file. Study 116886 (NCT02058589). GSK Study Register. Study entry at: https://www.gsk-studyregister.com/en/trial-details/?id=116886. **5.** Data on file. Study 116427 (NCT01798056). GSK Study Register. Study entry at: https://www.gsk-studyregister.com/en/trial-details/?id=116427. **6.** Data on file. Study 112673 (NCT01165203). GSK Study Register. Study entry at: https://www.gsk-studyregister.com/en/trial-details/?id=112673. **7.** Data on file. Study 110258 (NCT00920218). GSK Study Register. Study entry at: https://www.gsk-studyregister.com/en/trial-details/?id=110258.

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