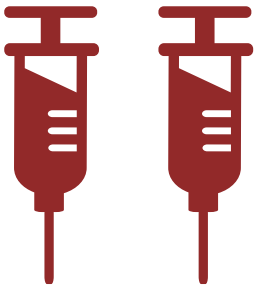
COMPLETING THE 2-DOSE SERIES OF SHINGRIX

According to the Prescribing Information, SHINGRIX should be administered on the following schedule: A first dose at Month 0 followed by a second dose anytime between 2 and 6 months later.[1] Every effort should be made to complete the 2-dose series as directed. GSK is dedicated to educating patients and providers about this schedule and facilitating timely series completion.

CDC GUIDANCE ON SHINGRIX DOSING SCHEDULE[2,3]



- Following the first dose of SHINGRIX, the second dose should be given 2-6 months later
- **If more than 6 months have elapsed since the first dose, administer the second dose as soon as possible. You should not restart the vaccine series**
- However:
  - —The efficacy of alternative dosing regimens has not been evaluated
  - —Data regarding the safety of alternative regimens are limited
  - —Individuals might remain at risk for herpes zoster during a longer than recommended interval between doses 1 and 2

In a phase 3 clinical study designed to help establish the dosing interval for SHINGRIX, all primary endpoints were met for dosing at a 0- and 6-month interval when compared to dosing at a 0- and 2-month interval. However, a co-primary endpoint (noninferiority) of the immune response was missed for dosing at a 0- and 12-month interval. (The upper limit of the 97.5% confidence interval was 1.53, above the predefined limit of <1.5.)[4]

GSK has not studied the safety or immune response of 3 doses of SHINGRIX in the indicated population (patients ≥50 years of age).[1]

CDC=Centers for Disease Control and Prevention.

For more information on the CDC recommendations for SHINGRIX and series completion resources, visit SHINGRIXHCP.com or contact the GSK Medical Information Department at 1-877-475-6448 (1-877-GSK-MI4U). Further information concerning the clinical study can be obtained via the GSK Medical Information Department.

- To report SUSPECTED ADVERSE REACTIONS, contact GSK at 1-888-825-5249 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You are encouraged to report vaccine adverse events to the US Department of Health and Human Services. Visit www.vaers.hhs.gov to file a report, or call 1-800-822-7967.

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

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

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

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

Please see accompanying full Prescribing Information.

References: 1. Prescribing Information for SHINGRIX. **2.** 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. **3.** Centers for Disease Control and Prevention. Frequently Asked Questions About Shingrix. https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/faqs.html. Updated August 22, 2018. Accessed September 11, 2018. **4.** Lal H, Poder A, Campora L, et al. Immunogenicity, reactogenicity and safety of 2 doses of an adjuvanted herpes zoster subunit vaccine administered 2, 6 or 12 months apart in older adults: results of a phase III, randomized, open-label, multicenter study. *Vaccine.* 2018;36(1):148-154.

SHINGRIX
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