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. 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**

- 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.)

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

**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.

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.