## STORAGE, RECONSTITUTION, AND ADMINISTRATION OF SHINGRIX[1]

Please refer to the full Prescribing Information for SHINGRIX for full details.

- Prior to reconstitution, store both the antigen (powder) and adjuvant (liquid) components refrigerated between 2° and 8°C (36° and 46°F). Discard if frozen and protect from light
- After reconstitution, administer immediately or store refrigerated between 2° and 8°C (36° and 46°F) for up to 6 hours. Discard if not used within 6 hours. Do not freeze; discard if frozen

**DO NOT FREEZE**

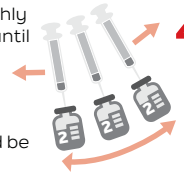
**Vial 1 of 2**
AS01$_B$ Adjuvant Suspension Component (liquid)

**Vial 2 of 2**
Lyophilized VZV gE Antigen Component (powder)

1 Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

2 Slowly transfer entire contents of syringe into the lyophilized gE antigen component vial (powder). Vial 2 of 2.

3 Gently shake the vial to thoroughly mix contents until powder is completely dissolved. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid.



4 After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly (IM).


Reconstituted Vaccine

VZV=varicella zoster virus; gE=glycoprotein E.

### Important Safety Information (cont'd)

- 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%)

**Please see Important Safety Information throughout and accompanying full Prescribing Information, also available at SHINGRIXHCP.com.**

## HOW SHINGRIX IS SUPPLIED[1]

1X

SHINGRIX is supplied as an outer carton of 1 dose (**NDC 58160-819-12**) containing:
- **Adjuvant Suspension Component (Vial 1 of 2) NDC 58160-829-01**
- **Lyophilized gE Antigen Component (Vial 2 of 2) NDC 58160-828-01**

10X

SHINGRIX is supplied as an outer carton of 10 doses (**NDC 58160-823-11**) containing:
- **Adjuvant Suspension Component (10 vials) NDC 58160-829-03**
- **Lyophilized gE Antigen Component (10 vials) NDC 58160-828-03**

## BILLING, CODING, AND INSURANCE

| | |
|---|---|
| **CPT Code** (Product): | **90750** |
| **CPT Code** (Administration) 1 vaccine administered: | **90471** |
| Each additional vaccine administered during same encounter: | **90472** |
| **ICD-10-CM Code** (Encounter for Immunization): | **Z23** |
| **Administration Modifier for Medicare:** | **GY** |
| **MVX Code:** | **SKB** |
| **CVX Code:** | **187** |

If you have any questions regarding SHINGRIX, call **1-800-772-9292** or visit **SHINGRIXHCP.com.**

### Important Safety Information (cont'd)

- 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 Important Safety Information throughout and accompanying full Prescribing Information, also available at SHINGRIXHCP.com.**

SHINGRIX (ZOSTER VACCINE RECOMBINANT, ADJUVANTED)





# SHINGRIX DELIVERED >90% EFFICACY AGAINST SHINGLES REGARDLESS OF AGE IN THOSE 50 YEARS AND OLDER[1,*]

- Age-related decline in immunity is a dominant driver of shingles[2-4]
- SHINGRIX is a vaccine for **intramuscular (IM) injection** only[1]
- Majority of solicited local and general adverse reactions to SHINGRIX had a median duration of 2-3 days[1,5,6]

*Data from the phase 3 ZOE-50 (≥50 years of age) trial (median follow-up period 3.1 years) and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials (median follow-up period 4 years) in subjects who received 2 doses of SHINGRIX (n=7344 and 8250, respectively) or placebo (n=7415 and 8346, respectively). These populations represented the modified Total Vaccinated Cohort, defined as patients who received 2 doses (0 and 2 months) of either SHINGRIX or placebo and did not develop a confirmed case of herpes zoster within 1 month after the second dose.[1,7]

### 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 Important Safety Information throughout and accompanying full Prescribing Information, also available at SHINGRIXHCP.com.**

## UNDERSTANDING SHINGLES & AGING

- 99% of people ≥50 years old are infected with the varicella zoster virus[8]
- In 1 out of 3 people, the dormant virus reactivates and causes shingles[2]
- As immunity against the virus decreases with age, the risk of reactivation increases[9]

## PATIENT ENGAGEMENT

### Identification

SHINGRIX is indicated for prevention of shingles in adults aged 50 years and older[1]

**THE CDC STATES THAT SHINGRIX IS[10]:**

- ☑ Recommended for the prevention of herpes zoster and related complications for immunocompetent adults aged ≥50 years
- ☑ Recommended for the prevention of herpes zoster and related complications for immunocompetent adults who previously received zoster vaccine live (ZVL)*

SHINGRIX is not indicated for the prevention of herpes zoster-related complications.[1]

***Important considerations[11]**

- There are limited data on vaccination with SHINGRIX in patients previously vaccinated with ZVL compared to those not previously vaccinated with ZVL
  - — 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
- There are no head-to-head clinical trials comparing the efficacy and safety of SHINGRIX to ZVL

CDC=Centers for Disease Control and Prevention.

**SHINGRIX**
**(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)**

**Please see Important Safety Information throughout and accompanying full Prescribing Information, also available at SHINGRIXHCP.com.**

## PATIENT ENGAGEMENT (CONT'D)

### Topics to Discuss With Your Patients

Inform patients of the potential benefits and risks of immunization with SHINGRIX.

| | |
|---|---|
| **Shingles Disease Risk** | • 99% of adults 50 years and older have had chickenpox, so the virus that causes shingles is already inside their body and can reactivate at any time[8]<br>• 1 out of 3 people in the US will get shingles in their lifetime[2] |
| **Indication** | SHINGRIX is a vaccine indicated for prevention of shingles in adults aged 50 years and older.[1]<br>SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).[1] |
| **Efficacy** | SHINGRIX delivered >90% efficacy against shingles regardless of age in those 50 years and older.[1] |
| **Safety and Tolerability** | Majority of solicited local and general adverse reactions to SHINGRIX had a median duration of 2-3 days.[1,5,6]<br>**Please see the "What to Expect" section for more information on discussing adverse reactions.** |

### Important Safety Information (cont'd)

- 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%)

**References: 1.** Prescribing Information for SHINGRIX. **2.** CDC. *MMWR.* 2008;57 (RR-5):1-30. **3.** Kimberlin DW, et al. *N Engl J Med.* 2007;356(13):1338-1343. **4.** Levin MJ. *Curr Opin Immunol.* 2012;24(4):494-500. **5.** Lal H, et al. *N Engl J Med.* 2015;372(22):2087-2096. **6.** Cunningham AL, et al. *N Engl J Med.* 2016;375(11):1019-1032. **7.** GSK Study Register. Study 113077 (NCT01165229). https://www.gsk-studyregister.com/en/trial-details/?id=113077. **8.** Kilgore PE, et al. *J Med Virol.* 2003;70(suppl 1):S111-S118. **9.** Weinberg A, et al. *J Infect Dis.* 2010;201(7):1024-1030. **10.** CDC. *MMWR.* 2018;67(3):103-108. **11.** Grupping K, et al. *J Infect Dis.* 2017;216(11):1343-1351.

**Please see Important Safety Information throughout and accompanying full Prescribing Information, also available at SHINGRIXHCP.com.**

## PATIENT ENGAGEMENT (CONT'D)

### Topics to Discuss With Your Patients (cont'd)

#### WHAT TO EXPECT

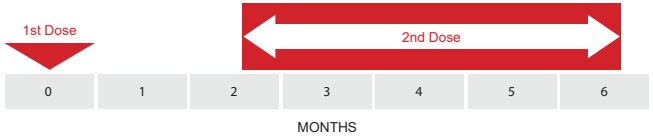
**It's important to inform the patient:**

Inform patients that they may experience side effects after receiving SHINGRIX. In clinical trials, the most common side effects were pain, redness, and swelling at the injection site, muscle pain, tiredness, headache, shivering, fever, and upset stomach.[1]

#### 2-DOSE SERIES

The efficacy of SHINGRIX was studied in patients who received 2 doses of the vaccine. Encourage your patients to schedule their second dose anytime between 2 and 6 months after their first dose.[1]

In order to stay on track, patients can sign up for a reminder at **SHINGRIXreminder.com**.




### Important Safety Information (cont'd)

- 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
- In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX

**Please see Important Safety Information throughout and accompanying full Prescribing Information, also available at SHINGRIXHCP.com.**