

## STORAGE, RECONSTITUTION, AND ADMINISTRATION OF SHINGRIX<sup>1</sup>

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

- Refrigerate between 2° and 8°C (36° and 46°F). Discard if frozen and protect from light
- Reconstitute and use immediately
- Reconstituted vaccine is stable for 6 hours refrigerated between 2° and 8°C (36° and 46°F), and should be discarded after 6 hours

### DO NOT FREEZE

**Vial 1 of 2**  
AS01<sub>B</sub> Adjuvant  
Suspension Component  
(blue-green cap/red ring)



**Vial 2 of 2**  
Lyophilized VZV gE  
Antigen Component  
(brown cap/green ring)



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



**2** Slowly transfer entire contents of syringe into the lyophilized antigen component in vial 2.



**3** Gently shake the vial to thoroughly mix contents until powder is completely dissolved. The reconstituted vaccine should be a pale brownish liquid.



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



VZV=varicella zoster virus; gE=glycoprotein E.

Reconstituted Vaccine

### 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 for SHINGRIX throughout and full Prescribing Information at SHINGRIXHCP.com.

## HOW SHINGRIX IS SUPPLIED<sup>1</sup>



SHINGRIX is supplied as an outer package 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



SHINGRIX is supplied as an outer package 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**

MX 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

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

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## ONLY SHINGRIX DELIVERS >90% EFFICACY REGARDLESS OF AGE IN THOSE 50 YEARS AND OLDER<sup>1,\*</sup>

### HOW MANY PATIENTS CAN YOU PROTECT?

- Age-related decline in immunity is a dominant driver of shingles<sup>2-4</sup>
- CDC states that SHINGRIX is preferred over ZVL for the prevention of herpes zoster and related complications<sup>5,†</sup>
- SHINGRIX is a recombinant vaccine for **intramuscular (IM) injection** only; **DO NOT FREEZE**<sup>1</sup>
- Majority of solicited local and general adverse reactions to SHINGRIX were transient with a median duration of 2-3 days<sup>1,6,7</sup>

\*Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-70 and ZOE-50 trials from subjects randomized to receive 2 doses of SHINGRIX (N=7698 and 8250, respectively) or placebo (N=7713 and 8346, respectively).<sup>1,6</sup>

†Please see CDC recommendations inside.

CDC=Centers for Disease Control and Prevention; ZVL=zoster vaccine live.

### 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 for SHINGRIX throughout and full Prescribing Information at SHINGRIXHCP.com.

## UNDERSTANDING SHINGLES & AGING

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

## PATIENT ENGAGEMENT

### Identification

SHINGRIX is indicated for prevention of shingles in adults aged 50 years and older.<sup>1</sup>

### THE CDC STATES THAT SHINGRIX IS<sup>5</sup>:

- ✓ 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)\***
- ✓ **Preferred over ZVL** for the prevention of herpes zoster and related complications\*

### \*Important Considerations<sup>10</sup>

- There are limited data on vaccination with SHINGRIX in patients 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



Please see Important Safety Information for SHINGRIX throughout and full Prescribing Information at [SHINGRIXHCP.com](http://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 people ≥50 years of age are at risk for developing shingles, and 1 out of 3 people will get shingles<sup>2,8</sup>
- The risk increases with age, especially after age 50 years<sup>2</sup>

#### Indication

SHINGRIX is a vaccine indicated for prevention of shingles in adults aged 50 years and older.<sup>1</sup>

#### Efficacy

Only SHINGRIX delivers >90% efficacy against shingles regardless of age in those 50 years and older.<sup>1</sup>

#### Safety and Tolerability

Majority of solicited local and general adverse reactions to SHINGRIX were transient with a median duration of 2–3 days.<sup>1,6,7</sup>

Please see the “What to Expect” section for more information on local reactions.

**References:** 1. Prescribing Information for SHINGRIX. 2. Centers for Disease Control and Prevention. Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2008;57(RR-5):1-30. 3. Kimberlin DW, Whitley RJ. Varicella-zoster vaccine for the prevention of herpes zoster. *N Engl J Med*. 2007;356(13):1338-1343. 4. Levin MJ. Immune senescence and vaccines to prevent herpes zoster in older persons. *Curr Opin Immunol*. 2012;24(4):494-500. 5. 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. 6. Lal H, Cunningham AL, Godeaux O, et al, for the ZOE-50 Study Group. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med*. 2015;372(22):2087-2096. 7. Cunningham AL, Lal H, Kovac M, et al, for the ZOE-70 Study Group. Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. *N Engl J Med*. 2016;375(11):1019-1032. 8. Kilgore PE, Kruszon-Moran D, Seward JF, et al. Varicella in Americans from NHANES III: implications for control through routine immunization. *J Med Virol*. 2003;70(suppl 1):S111-S118. 9. Weinberg A, Lazar AA, Zerbe GO, et al. Influence of age and nature of primary infection on varicella-zoster virus-specific cell-mediated immune responses. *J Infect Dis*. 2010;201(7):1024-1030. 10. Gruppung 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. 11. Immunization Action Coalition. Medical Management of Vaccine Reactions in Adult Patients. <http://www.immunize.org/catg.d/p3082.pdf>. Accessed March 15, 2018.

Please see Important Safety Information for SHINGRIX throughout and full Prescribing Information at [SHINGRIXHCP.com](http://SHINGRIXHCP.com).

## PATIENT ENGAGEMENT (CONT'D)

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



#### WHAT TO EXPECT

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

You may experience local adverse reactions after receiving SHINGRIX. In clinical trials, the most common local adverse reactions were pain, redness, and swelling at the injection site. The most common general adverse events were myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.<sup>1</sup>

Because each patient's clinical situation is unique, GSK has no specific recommendations on adverse reaction management. GSK recommends healthcare professionals (HCPs) use their clinical judgment. Specific management of adverse reactions was not studied in the clinical trials of SHINGRIX.

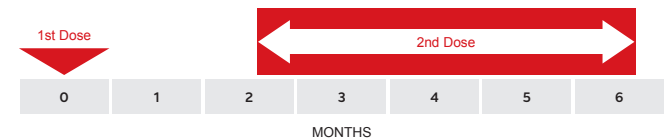
The Immunization Action Coalition (IAC) recommends if localized reaction occurs, such as soreness, redness, itching, or swelling at the injection site, to apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication. These are general recommendations from IAC and have not been evaluated with SHINGRIX.<sup>11</sup>



#### 2-DOSE SERIES

The efficacy of SHINGRIX was only studied in patients who received 2 doses of the vaccine.<sup>1</sup> In order for your patients to experience similar results, encourage them to schedule their second dose anytime between 2 and 6 months after their first dose.

In order to stay on track, patients can sign up for a reminder at [SHINGRIXreminder.com](http://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

Please see Important Safety Information for SHINGRIX throughout and full Prescribing Information at [SHINGRIXHCP.com](http://SHINGRIXHCP.com).