#### **Zoster Vaccine:**

#### Immunize.org Answers Your Questions

For complete information on CDC's recommendations for the use of zoster vaccine, go to www.immunize.org/acip

Experts from Immunize.org answer your questions about zoster vaccine. You'll find additional Q&As about zoster vaccine on the "Ask the Experts" section of immunize.org at www.immunize.org/askexperts/experts\_zos.asp.

### Please describe the zoster vaccine available in the United States.

Recombinant zoster vaccine (RZV; Shingrix, GSK) was licensed for the prevention of herpes zoster by FDA for use in the United States in 2017. Shingrix has not been evaluated for the prevention of chickenpox. It contains one piece of the varicella zoster virus (VZV) in combination with an adjuvant (AS01B) to enhance the immune response to the vaccine. It does not contain any live virus. Shingrix is administered as a 2-dose series by the intramuscular route. The second dose should be given 2 to 6 months after the first dose, with a minimum interval of 1 month (4 weeks) between doses.

Zoster vaccine live (ZVL, Zostavax, Merck) is a 1-dose, live attenuated vaccine that was licensed by the FDA in 2006, but has not been available in the United States since November 2020. See references for more details.

#### To whom should zoster vaccine be given?

The Advisory Committee on Immunization Practices (ACIP) recommends a 2-dose series of Shingrix for

- all people age 50 years and older
- people age 19 years and older who are or will be immunodeficient or immunocompromised (have a weakened immune system because of disease or therapy)

People age 50 or older who are not immunocompromised should be vaccinated whether or not they had a prior episode of

herpes zoster or recall having chickenpox. People who have previously received Zostavax should receive a Shingrix vaccination series beginning at least 8 weeks after their dose of Zostavax. People who are immunocompromised should have a history of disease, varicella vaccination, or laboratory evidence of immunity.

## Is there an upper age limit for receipt of the zoster vaccine?

There is no upper age limit for receiving zoster vaccine. The incidence of herpes zoster increases with increasing age; about 50% of people living until age 85 years will develop zoster. ACIP recommends the vaccine for everyone age 50 and older and people 19 years and older who are or will have a weakened immune system due to disease or treatment for disease.

# Why are people with immunocompromising conditions recommended for Shingrix?

The risk of shingles and shingles-related complications is higher in immunocompromised people, including among young adults who are immunocompromised. The Shingrix vaccine contains no live virus, only a piece of the virus, and can safely be given to people with weakened immune systems.

# Before administering zoster vaccine is it necessary to ask (or test) if the person has ever had chickenpox or shingles?

People age 50 years or older who are not immunocompromised should be given Shingrix unless they have a medical contraindication to vaccination (described below). A history of chickenpox or testing for varicella antibody before giving the vaccine is not necessary.

People who are age 19 or older and immunocompromised should be evaluated for evidence of immunity to chicken-pox before vaccination with Shingrix

because the ability of Shingrix to prevent chickenpox (primary varicella infection) has not been studied. See www.cdc.gov/shingles/vaccination/immunocompromised-adults.html for detailed clinical guidance on the use of Shingrix in immunocompromised adults.

# What are the contraindications and precautions to zoster vaccine?

The only contraindication for Shingrix is a severe allergic reaction to a vaccine component. The presence of a moderate or severe acute illness is a precaution. Vaccination should be deferred until the illness improves. There is currently no ACIP recommendation for use of Shingrix in pregnancy; therefore, providers should consider delaying Shingrix until after pregnancy. There is no recommendation for pregnancy testing before vaccination. Clinicians may consider vaccinating people who are breastfeeding if Shingrix is otherwise indicated.

# When should zoster vaccine be given to someone who is immunocompromised?

Ideally, patients should get zoster vaccine before becoming immunosuppressed. For example, a person likely to require an organ transplantation or at risk of endstage renal disease, or who may start immunosuppressing treatment for autoimmune disease may be considered for vaccination prior to becoming immunosuppressed.

### By what route should zoster vaccine be administered?

Shingrix should be administered by the intramuscular route in the deltoid or anterolateral thigh muscle.

# How effective is zoster vaccine in preventing shingles?

In the key pre-licensure clinical trial of Shingrix, recipients age 50 years and older

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had a 98% reduction in shingles compared to placebo recipients. In a separate trial among people age 70 years and older, Shingrix recipients had an 89% reduction in shingles compared to placebo recipients. In both trials postherpetic neuralgia (persistent nerve pain after the zoster rash resolves) was reduced by 86% to 100%.

In general, Shingrix has moderate to high effectiveness against herpes zoster and postherpetic neuralgia in people who are immunocompromised. The effectiveness and durability of protection provided by Shingrix will vary depending upon the cause and the severity of immunocompromise in a given individual.

# What adverse reactions have been reported with Shingrix?

In pre-licensure clinical trials of Shingrix the most common adverse reactions were pain at the injection site (78%), myalgia (45%), and fatigue (45%). Any grade 3 adverse event (reactions related to vaccination which were severe enough to prevent normal activities) was reported in 17% of vaccine recipients compared with 3% of placebo recipients. Grade 3 injectionsite reactions (pain, redness, and swelling) were reported by 9% of vaccine recipients, compared with 0.3% of placebo recipients. Grade 3 solicited systemic events (myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms) were reported by 11% of vaccine recipients and 2.4% of placebo recipients. The occurrence of local grade 3 reactions did not differ by vaccine dose; however, systemic grade 3 reactions were reported more frequently after dose 2.

Rates of serious adverse events (an undesirable experience associated with the vaccine that results in death, hospitalization, disability or requires medical or surgical intervention to prevent a serious outcome) were similar in vaccine and placebo groups.

# What should I advise my patients about adverse reactions after Shingrix?

Before vaccination, providers should counsel Shingrix recipients about expected systemic and local adverse reactions (described above). Reactions to the first dose do not strongly predict reactions to the second dose. Shingrix recipients should be encouraged to complete the series even if they experienced a grade 3 reaction to the first dose.

### How can I assure that my patients receive both doses of Shingrix on time?

Many clinics have implemented reminder systems in their practice to help assure their patients complete the 2-dose schedule. This can be enabled by software at the clinic, pharmacy, or immunization information system. The system can generate a list of patients that might be coming due (or past due) for second doses or can appear on the clinic's electronic health record as an alert for the provider.

With this information, clinic or pharmacy personnel can send electronic, telephone, or written reminders to recipients of the first dose, to encourage adherence with the second dose. Regardless of the manner chosen, it's important that patients receive both doses to get the maximum benefit from the vaccine.

#### How should Shingrix be stored?

Both the Shingrix adjuvant suspension (diluent) and the lyophilized antigen component must be stored refrigerated between 2°C and 8°C (36°F and 46°F). The vials should be protected from light. Neither the diluent nor antigen should be frozen. Discard if either vial has been frozen.

After reconstitution, administer Shingrix immediately or store refrigerated between 2°C and 8°C (36°F and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours. Do not freeze. Discard if the vaccine has been frozen.

#### How should zoster vaccine be transported to an off-site clinic location?

Shingrix should be stored at refrigerator temperature. Transport of refrigerated vaccines is described in detail in the CDC *Storage and Handling Toolkit*, available at www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

#### REFERENCES

Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. CDC. Morbidity and Mortality Weekly Report (MMWR) January 21, 2022; 71(3):80–84, available at www. cdc.gov/mmwr/volumes/71/wr/pdfs/mm7103a2-H.pdf.

Recommendations of the Advisory Committee on Immunization Practices (ACIP) for Use of Herpes Zoster Vaccines. CDC. *MMWR*, January 26, 2018;67(No.3): 103-8, available at www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6703a5-H.pdf.

Clinical Considerations for Use of Recombinant Zoster Vaccine (RZV, Shingrix) in Immunocompromised Adults Aged ≥19 Years, available at www.cdc.gov/shingles/vaccination/immunocompromised-adults.html.

