Shingles Vaccine: FAQs

(Updated March 2022)

The FAQ below addresses common clinical questions about the herpes zoster or shingles vaccines (*Shingrix*, *Zostavax II* [Canada]).

Question	Answer/Pertinent Information
What information should you know about the **recombinant zoster vaccine** (RZV; *Shingrix*)?	• **Vaccine type**:[13,14] RECOMBINANT, non-live, adjuvanted[c] (to boost immunity) vaccine. • **Dosing**:[13,14] two IM doses 0.5 mL each. Second dose given two to six months AFTER the first dose. o If giving to a patient who is or will be immunocompromised and the patient would benefit from a shorter immunization schedule, the second dose can be given 4 weeks (one month) AFTER the first dose.[13,14,17] o Series does NOT need to be restarted if more than six months have elapsed between the first and second dose. o The second dose should be repeated if given less than four weeks after the first dose.[17] o It is NOT necessary to re-administer *Shingrix* if accidentally given subcutaneously instead of IM.[17] • **Adverse Reactions**: o Incidence of injection site pain:[13,14,b] 69% to 88% o Systemic reactions occurring more commonly than with placebo:[13,14] myalgia, fatigue, headache, fever/chills, GI o Adverse reactions with the first dose are not strongly predictive of adverse reactions to the second dose.[17] However, headache and chills may be more common with the second dose compared to the first.[13] • **Storage**:[13,14] 36°F to 46°F (2°C to 8°C) (lyophilized antigen [vaccine] and adjuvant suspension [diluent]) • **Reconstitution and stability**:[13,14] Reconstitute with the diluent provided and use immediately or refrigerate between 36°F and 46°F (2°C and 8°C) and use within six hours.
What information should you know about the **live-attenuated zoster vaccine** (ZVL; *Zostavax II* [Canada])?	• **Vaccine type**:[3] LIVE-ATTENUATED vaccine • **Dosing**:[3] single subcutaneous dose 0.65 mL • **Adverse Reactions**: o Incidence of injection site pain:[3,a,b] 54% o Systemic reaction occurring more commonly than with placebo:[3,a] headache • **Storage**:[3] 2°C to 8°C or colder (vaccine); 2°C to 8°C or 20°C to 25°C (diluent) • **Reconstitution and Stability**:[3] reconstitute with the diluent provided and use within 30 minutes of reconstitution.
At **what age** should the shingles vaccine be given? *Continued...*	• Risk of getting zoster or prolonged PHN pain rises with age, primarily after 60 years of age.[5,8] • *Shingrix* is the preferred shingles vaccine.[2,27,28] Vaccination with *Shingrix* is recommended: o for people ≥50 years old.[2,13,14,28] o for adults ≥19 years old (≥18 years [Canada]) considered at risk for shingles and who are or will be immunocompromised due to disease or therapy.[14,34,35]

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Question	Answer/Pertinent Information
Appropriate age to vaccinate, continued	o even in patients who have previously been vaccinated with *Zostavax* (previously available in the U.S. until November 18, 2020) or *Zostavax II* (Canada).[2,28] ▪ Give *Shingrix* (full series) as early as one year after *Zostavax II* (Canada) [Evidence Level C], but especially if it has been >5 years since *Zostavax* (not available in U.S. since November 18, 2020) or *Zostavax II* was given (most of the protection is lost by then).[2,9,27,28] • *Zostavax II* is Health Canada-approved and guideline recommended for people 50 years of age and older.[2,3] o It is NOT known if vaccination between the ages of 50 to 59 provides ongoing protection at older ages when zoster incidence and risk of complications is higher.[2] (See duration of *Zostavax II* immunity below.)
Should **patients who've had shingles** receive the vaccine?	• For **immunocompetent patients** with an indication for *Shingrix*, vaccination is recommended regardless of shingles or chickenpox history.[2,28] o More than 99% of adults ≥50 years old have been exposed to the varicella-zoster virus.[28] • Yes, immunocompromised patients ≥19 years old (≥18 years old [Canada]) who've previously been diagnosed with shingles by a healthcare provider should receive *Shingrix*.[35] • Different safety concerns are not expected in persons with a history of shingles.[2,12]
How long **after a shingles episode** can the vaccine be given?	• Re-occurrence risk is low for up to 18 months after shingles due to residual immunity in immunocompetent patients.[10] • **CDC**: Wait until the acute stage shingles illness is over (i.e., symptoms subsided) to be vaccinated with *Shingrix*.[28] • **NACI**: Wait until one year has elapsed between the last shingles episode and zoster vaccination.[2] o Herpes ophthalmicus has recurred following shingles vaccination (*Zostavax II*).[2] Causality has NOT been established, but inform patients that the risk/benefit is unknown.[2]
Can the shingles vaccine be **administered with other vaccines or medications**?	• ***Shingrix*** can be given concomitantly (at separate sites) with live or inactivated vaccines, including the pneumococcal vaccine and Tdap [Evidence Level B-1].[2,16,17,27] o There are theoretical concerns about more side effects when giving two adjuvanted vaccines at the same time.[15] ▪ Co-administration with adjuvanted flu vaccines (e.g., *Fluad*) has not been studied. However, don't delay vaccination if only an adjuvanted flu vaccine is available.[15] If an adjuvanted flu vaccine needs to be given with *Shingrix*, administer at separate sites.[15] • ***Zostavax II*** can be given concomitantly (at separate sites) with other live and inactivated vaccines.[2] o If *Zostavax II* is not given simultaneously (at separate injection sites) with **another live injectable vaccine**, separate the vaccines by ≥4 weeks.[2] Four-week separation does NOT apply to live oral or intranasal vaccines.[2] o When possible, administer *Zostavax II* ≥24 hours after discontinuation of an antiviral agent active against herpes viruses (acyclovir, famciclovir, etc). Avoid restarting the antiviral for at least 14 days after vaccination.[2] ▪ This is NOT a concern with *Shingrix*, as it is a recombinant vaccine (e.g., does not contain live virus).[17]

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Question	Answer/Pertinent Information

How long does **immunity** last?	***Shingrix***
	• Immune response appears to be maintained at least nine years after vaccination based on cellular response.[20,21]
	  o It is unclear if this correlates to continued protection against shingles and PHN.[20,21]
	• Maintains >90% efficacy regardless of age at least four years after vaccination.[19]
	  o Maintains about 88% efficacy four years after vaccination in patients vaccinated at 70 years of age or older.[7]
	Zostavax II
	• Protection against zoster seems to last up to three years. Efficacy five years after vaccination is not known.[2]
	• Though studies are ongoing, there is no current recommendation for a booster or revaccination.[2]

How **effective** is the shingles vaccine?	**Shingles**
	• *Shingrix*: NNT ~37 patients to prevent one case of shingles over about three years in patients ≥50 years old.[11]
	  o Clinical trials have NOT been conducted to evaluate the efficacy of *Shingrix* if just one dose is received.[26]
	  o There is insufficient data available from post-hoc analyses to accurately predict the efficacy of *Shingrix* in patients that have only received one dose.[26]
	• *Zostavax II* NNT: ~59 patients to prevent one case of shingles over about three years in patients >60 years old.[3,a]
	Postherpetic neuralgia (PHN)
	• All available vaccines have an NNT ~350 to prevent one case of PHN over about three years.[7,25]

What are **considerations for immunocompromised patients** and the shingles vaccine?
 	
Continued...
	Shingrix (Canada: generally preferred over the live shingles vaccines in immunocompromised patients.[22])
	• Data are growing about the safety and efficacy in immunocompromised patients, specifically in patients with HIV, hematologic cancers, post-transplant (renal and hematologic), and during chemotherapy.[13,14,29-32]
	  o *Shingrix* is approved for use in adults ≥19 years old (≥18 years old [Canada]) **who are considered at risk for shingles and are or will be immunocompromised due to disease or therapy**.[13,14,34]
	    ▪ **patients ≥50 years old** (age group has a higher baseline risk of PHN[37]): recommend vaccination in patients with low- or high-level immunosuppression.[13,14,34,38,e]
	    ▪ **patients 19 to 49 years old (Canada: 18 to 49 years old)** (age group has a lower baseline risk of PHN[37]):
	      • **recommend** vaccination in patients with high-level immunosuppression.[38,e]
	      • **consider use** (weighing possible benefits and risks) in patients with low-level immunosuppression (e.g., taking prednisone chronically at doses <20 mg/day).[38,e]
	  o Assess and document the need for *Shingrix* vaccination (varicella immunity) using one of the following: previously received two doses of a varicella vaccine, lab evidence of immunity or confirmation of disease, or diagnosis or verification of a history of chicken pox or shingles by a healthcare provider.[35,f]
	  o If giving *Shingrix* as a part of a standing order, consider involving the medical director or the patient's prescriber for the immunocompromising condition.[36]
	  o Optimal timing of *Shingrix* vaccination may vary based on the patient's immunocompromising condition. CDC provides guidance on timing at https://www.cdc.gov/shingles/vaccination/immunocompromised-adults.html.[35]

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Question	Answer/Pertinent Information

Immunocompromised patients, continued	***Zostavax II*** (Canada)
	• Contraindicated (expert consultation is advised in complex cases) in patients with:[2,3,22]
	  o primary immune deficiency (e.g., disorders of T-cell function)
	  o acquired immune deficiency (e.g., blood dyscrasia, chemotherapy, radiation therapy, organ or stem cell transplant, cancer affecting the bone marrow or lymphatics, HIV if CD4 count is <200 10^6 cells/L).
	  o leukocyte adhesion defect, Chediak-Higashi syndrome and other defects in cytotoxic granule release, and in undefined phagocytic cell defects.
	• When indicated (though *Shingrix* is preferred) can give to patients:[22]
	  o with complement deficiency, neutropenia, or certain phagocytic defects (e.g., chronic granulomatous disease), or HIV with CD4 counts ≥200 x 10^6/L.[22]
	  o taking antitumor necrosis factor biologics (TNF inhibitors), or on low-level immunosuppressive therapy (e.g., less than 14 days' corticosteroid use, prednisone <20 mg daily or its equivalent, topical or inhaled corticosteroid, corticosteroid joint injection, methotrexate ≤0.4 mg/kg/week, azathioprine ≤3 mg/kg/day, or 6-mercaptopurine ≤1.5 mg/kg/day).[18,22]
	  o at least four weeks before immunosuppressive therapy, four weeks after high-dose corticosteroids, or three months after other immunosuppressive drugs (e.g., cyclosporine, chemo).

What are **considerations for pregnant and lactating patients** and the shingles vaccine?	• It is generally not necessary to avoid being around pregnant patients or young children after receiving either shingles vaccine, as there are not any documented cases of transmission from vaccinated adults.[33] o **If a patient develops a rash** after receiving a live zoster vaccine (*Zostavax II*), recommend covering the rash until the bumps crust over as a precaution against possible transmission.[33] ***Shingrix*** • There are not enough data available to establish if there is risk with use in pregnant or breastfeeding patients.[13,14] ***Zostavax II*** • Contraindicated during pregnancy.[2,3] • Patients should not become pregnant until at least three months after getting the vaccine.[2,3]
What are **COVID-19 pandemic-related considerations** with the shingles vaccine?	• In the **U.S.**:[23] Continue to give due or overdue shingles vaccine doses during the pandemic. o Vaccine series does NOT need to be restarted if more than six months have elapsed since the first dose before the second dose is given.[17] • In **Canada**:[24] When possible, combine the shingles vaccination visit with another medical visit, to limit possible COVID-19 exposure risk. Consider deferring the second dose of *Shingrix* up to six months (12 months between the first and second dose). Base the timing of the second vaccination on local COVID-19 community transmission risk. • See our chart, *FAQs: Immunizations During COVID-19*, for answers to common questions, including guidance on counseling patients about systemic side effects that might mimic COVID-19 symptoms.

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Question	Answer/Pertinent Information
In the U.S., what are cost considerations with the shingles vaccine?	• *Shingrix* costs about $340 total for the two-dose series and is covered by:[1,4,d] o Medicare Part D or Medicare Advantage Plan Part C o most private insurance plans (i.e., for patients between the ages of 50 and 65)
In Canada, what are cost considerations with the shingles vaccine?	• In Ontario, patients 65 to 70 years of age can receive *Shingrix* free of charge from their primary care provider (transitioned from providing *Zostavax II* to *Shingrix* in October 2020).[6] Patients who:[6] o received publicly funded *Zostavax II* are NOT eligible to receive publicly funded *Shingrix.* o paid out-of-pocket for *Zostavax II* ARE eligible to receive publicly funded *Shingrix*. o were born in 1949 or 1950 but missed the chance to receive the publicly funded shingles vaccine due to the COVID-19 pandemic are eligible to receive *Shingrix* through this program. o are from other provinces or who do NOT meet the age criteria can pay about $280 for the two-dose *Shingrix* series (preferred over *Zostavax II*[2]) or about $200 for *Zostavax II*.[d]

a. *Zostavax II* product monograph references U.S. efficacy and adverse reaction trial data from *Zostavax* (no longer available in the U.S. as of November 18, 2020).[3]
b. *Shingrix* causes more injection site pain; however, *Zostavax II* causes more redness and swelling (indirect comparisons).[3,13,a]
c. *Quillaja saponaria* Molina, fraction 21 (QS-21), and 3-0-desacyl-4-monophosphoryl lipid A (MPL) act as adjuvants to boost immune response.[13,14]
d. Pricing based on wholesale acquisition cost (WAC). U.S. medication pricing by Elsevier, accessed March 2021 (March 2022 for *Shingrix*).
e. In general, patients with higher levels of immunosuppression (e.g., hematopoietic stem cell transplant recipients) have a higher risk of developing shingles than patients with lower levels of immunosuppression (e.g., people living with HIV, autoimmune or inflammatory conditions).[37]
f. When there is no available documentation of varicella immunity, consider other factors to weigh risks and benefits for *Shingrix* vaccination (e.g., does patient recall having the chicken pox, is it highly likely that the patient previously had the chicken pox [e.g., born before 1980]).[35] Patients without varicella immunity would be at risk of chicken pox, not shingles.

Abbreviations: CDC = Centers for Disease Control and Prevention; FDA = U.S. Food and Drug Administration; GI = gastrointestinal (e.g., nausea, vomiting, diarrhea, abdominal pain); HIV = human immunodeficiency syndrome; NACI = National Advisory Committee on Immunization; NNT = number needed to treat; PHN = postherpetic neuralgia.

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Levels of Evidence

In accordance with our goal of providing Evidence-Based information, we are citing the **LEVEL OF EVIDENCE** for the clinical recommendations we publish.

Level	Definition	Study Quality
A	Good-quality patient-oriented evidence.*	1. High-quality randomized controlled trial (RCT) 2. Systematic review (SR)/Meta-analysis of RCTs with consistent findings 3. All-or-none study
B	Inconsistent or limited-quality patient-oriented evidence.*	1. Lower-quality RCT 2. SR/Meta-analysis with low-quality clinical trials or of studies with inconsistent findings 3. Cohort study 4. Case control study
C	Consensus; usual practice; expert opinion; disease-oriented evidence (e.g., physiologic or surrogate endpoints); case series for studies of diagnosis, treatment, prevention, or screening.	

***Outcomes that matter to patients** (e.g., morbidity, mortality, symptom improvement, quality of life).

[Adapted from Ebell MH, Siwek J, Weiss BD, et al. Strength of Recommendation Taxonomy (SORT): a patient-centered approach to grading evidence in the medical literature. *Am Fam Physician* 2004;69:548-56. http://www.aafp.org/afp/2004/0201/p548.pdf.]

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