STORAGE AND RECONSTITUTION OF SHINGRIX[1]

- For both lyophilized gE vial and adjuvant solution vial, store in a refrigerator (2°C to 8°C)
- Do **NOT** freeze
- Store in the original package in order to protect from light
- After reconstitution, the vaccine should be used promptly
  - If this is not possible, the vaccine should be stored in a refrigerator (2°C to 8°C)
  - If not used within 6 hours it should be discarded

HOW SHINGRIX IS SUPPLIED[1]

SHINGRIX is supplied as a pack size of 1 dose containing:

- Adjuvant suspension in a vial (type I glass) with a stopper (butyl rubber), with blue-green caps (vial 1 of 2)
- Lyophilized gE in a vial (type I glass) with a stopper (butyl rubber), with brown caps (vial 2 of 2)

Packaged without syringes or needles.

SHINGRIX is supplied as a pack size of 10 doses containing:

- Adjuvant suspension in a vial (type I glass) with a stopper (butyl rubber), with blue-green caps (10 vials)
- Lyophilized gE in a vial (type I glass) with a stopper (butyl rubber), with brown caps (10 vials)

Packaged without syringes or needles.

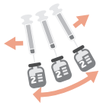
Step-by-step reconstitution instructions for SHINGRIX[1]

Vial 1 of 2
$AS01_B$ Adjuvant Suspension Component (liquid; blue green cap/red ring)

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

STEP 1: Withdraw the entire content of **vial 1** containing the suspension into a sterile syringe.

STEP 2: Add the entire contents of the syringe into **vial 2** containing the lyophilized powder.



STEP 3: Shake gently until the lyophilized powder is completely dissolved. It should be an opalescent, colourless to pale brownish liquid.

Inspect the vaccine for any foreign particulate matter and/or variation of appearance. If either is observed, do not administer the vaccine.

STEP 4: Withdraw the entire contents of the vial containing the reconstituted vaccine into a sterile syringe.

Change the needle so that you are using a new needle to administer the vaccine.

gE=glycoprotein E; VZV=varicella zoster virus.

SHINGRIX is to be reconstituted only with the accompanying adjuvant suspension. After reconstitution, the vaccine should be used promptly; if this is not possible, the vaccine should be stored in a refrigerator (2°C to 8°C). If not used within 6 hours, it should be discarded.[1]

HELP PROTECT PATIENTS 50 YEARS AND OLDER FROM SHINGLES WITH SHINGRIX[1]

The cost of SHINGRIX may be covered by your patients' private insurance. Advise them to contact their insurance provider and give the DIN (drug identification number) below to find out.

Visit **THINKSHINGRIX.CA** to learn more

SHINGRIX DIN: 02468425

References: 1. SHINGRIX Product Monograph, GlaxoSmithKline Inc., June 3, 2020. **2.** Lal H *et al.* Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med* 2015 May;372(22):2087-2096. **3.** Cunningham AL *et al.* Efficacy of the herpes zoster subunit vaccine in adults 70 years of age or older. *N Engl J Med* 2016 Sep;375(11):1019-1032. **4.** Harpaz R, Ortega-Sanchez IR, Seward JF; Advisory Committee on Immunization Practices (ACIP), Centers for Disease Control and Prevention (CDC). Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep* 2008;57(RR-5):1-30. **5.** Government of Canada. Canadian Immunization Guide: Part 4 – Active Vaccines. Available at: https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-8-herpes-zoster-(shingles)-vaccine.html. **6.** Weinberg A *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. **7.** Kawai K, Gebremeskel BG, Acosta CJ. Systematic review of incidence and complications of herpes zoster: towards a global perspective. *BMJ Open* 2014;4(6):e004833. **8.** National Advisory Committee on Immunization (NACI). Statement on the recommended use of herpes zoster vaccine. *Can Commun Dis Rep* 2010;36(ACS-1):1-19. **9.** Public Health Agency of Canada. An Advisory Committee Statement (ACS), National Advisory Committee on Immunization (NACI) – Updated Recommendations on the Use of Herpes Zoster Vaccines. Ottawa, Ontario: Public Health Agency of Canada; June 2018. Available at: https://www.canada.ca/en/services/health/publications/healthy-living/updated-recommendations-use-herpes-zoster-vaccines.html. **10.** Reproduction of information from the Protocole d'immunisation du Québec, 7th ed. Zona-SU section. Available at: http://www.msss.gouv.qc.ca/professionnels/vaccination/piq-vaccins/zona-su-vaccin-sous-unitaire-contre-le-zona/. The original French version of this information was published in 2018 by the Department of Health and Social Services. The Department declines any responsibility for any damage, loss, or injury that may result from this translation into English. In case of contradiction between the English and French versions of this information, the latter will prevail. The Government of Quebec is and remains the only copyright owner of the work in French. The English version has not been validated by the Ministry of Health and Social Services. **11.** Data on file. Ipsos Market Research, 2019. GlaxoSmithKline Inc.

SHINGRIX
HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, $AS01_B$, ADJUVANTED)

04162
04/21

POCKET GUIDE

SHINGRIX DEMONSTRATED >90% EFFICACY AGAINST SHINGLES IN THOSE 50 YEARS AND OLDER VS. PLACEBO[1-3*]

- **97.2% ≥50 years overall** (95% CI: 93.7, 99.0; 6/7,344 vs. 210/7,415; data from ZOE-50)†
- **91.3% ≥70 years overall** (95% CI: 86.8, 94.5; 25/8,250 vs. 284/8,346; pooled data from ZOE-50 and ZOE-70)†

SHINGRIX: START THE CONVERSATION WITH YOUR PATIENTS

- Information about shingles
- NACI recommendations
- SHINGRIX dosing and administration
- SHINGRIX safety information
- And more

Are your patients 50+ aware of their risk of shingles?
(see page 3 for more information)

Indication and Clinical Use:

SHINGRIX is indicated for prevention of herpes zoster (HZ, or shingles) in adults 50 years of age or older.[1]

NACI=National Advisory Committee on Immunization

*Two multi-centre, randomized, observer-blind, placebo-controlled trials in subjects 50 years of age and older who received two doses of SHINGRIX (n=14,645) or placebo (n=14,660) at 0 and 2 months. Primary efficacy analysis was of the modified Total Vaccinated Cohort (mTVC): all subjects randomized who received a second dose of the vaccine and did not develop a confirmed case of shingles within one month after the second dose. Randomization was stratified by age in years: 50–59, 60–69, 70–79 and ≥80 in an 8:5:3:1 ratio (ZOE-50); 70–79, ≥80 in a 3:1 ratio (ZOE-70). Subjects were followed for the development of shingles for a median of 3.1 years (ZOE-50; range: 0–3.7 years) and 3.9 years (ZOE-70; range: 0–4.5 years). Primary endpoint was vaccine efficacy as measured by the reduction in herpes zoster risk.[1-3]

†Vaccine efficacy (VE) adjusted by age strata and region.

SHINGRIX
HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, $AS01_B$, ADJUVANTED)

Important Safety Information

Contraindications:

Patients with a known hypersensitivity to the active substance or to any component of the vaccine

Most serious warnings and precautions:

- **Administration:** Do not administer the vaccine intravascularly, intradermally, or subcutaneously

Other relevant warnings and precautions:

- A protective immune response may not be elicited in all vaccinees
- Not for prevention of primary varicella infection, or treatment of HZ or postherpetic neuralgia
- Postpone in those with acute, severe febrile illness
- Use with caution in those with thrombocytopenia or any coagulation disorder
- Syncope following or before any vaccination as a psychogenic response
- Fever and shivering were more frequent when the 23-valent pneumococcal polysaccharide (PPV23) vaccine was co-administered with SHINGRIX
- Use in special populations, such as pregnant or nursing women or pediatrics (<18 years of age), has not been established
- Limited data in immunocompromised adults 50 years of age or older

Adverse events:

- Solicited local and general adverse reactions that occurred in clinical trials within 7 days of vaccination in subjects aged 50–69 and ≥70 years, respectively, were: pain (85.6%, 69.2%), redness (38.5%, 37.7%), swelling at the injection site (28.5%, 23.0%), myalgia (53.0%, 35.1%), fatigue (51.3%, 36.6%), headache (45.2%, 29.0%), shivering (33.1%, 19.5%), fever (25.9%, 14.3%), gastrointestinal symptoms (20.5%, 13.5%)
- Unsolicited adverse reactions that occurred in clinical trials within 30 days of vaccination in ≥1% of subjects and ≥2-fold higher than placebo recipients included chills (3.5%), injection site pruritus (2.2%), and malaise (1.7%)
- Post-market adverse reactions are: hypersensitivity reactions (rare), including rash, urticaria, angioedema

For more information:

Please consult the product monograph at **gsk.ca/SHINGRIX/PM** for important information relating to dosing and administration, adverse reactions, contraindications and drug interactions which have not been discussed in this piece. To request a product monograph, or to report an adverse event please call **1-800-387-7374**.

ABOUT SHINGLES

Age

Increasing age causes a natural decline in immunity.[4]

- **2/3 of shingles cases occur in those over the age of 50[5]**

Immunity

There is a reduction in the number and functionality of immune cells that prevent reactivation of varicella zoster virus.[4,6]

Shingles

This leads to an increase in the incidence and severity of shingles.[4]

Approximately 1 out of 3 people will develop shingles during their lifetime, due to a reactivation of the dormant virus – a blistering rash that can be accompanied by burning, stabbing, or shock-like pain.[4,7]

≥90% of Canadians have had varicella and are at risk for shingles.[8]

NACI RECOMMENDATIONS

The National Advisory Committee on Immunization (NACI) recommends that SHINGRIX should be offered to adults 50 years of age and older **(strong recommendation)**.[9]

According to NACI, a strong recommendation applies to most individuals and should be followed, unless a clear and compelling rationale for an alternative approach is present.[9]

Refer to the NACI statement on the Public Health Agency website for further information.

THE CIQ RECOMMENDATION

The Comité sur l'immunisation du Québec (CIQ) preferentially recommends SHINGRIX for adults 50 years of age and older.[10]

ENGAGING WITH YOUR PATIENTS

Topics to Discuss with Your Patients

The pain of shingles can last for weeks,[4] but it only takes a moment to start a conversation about SHINGRIX. Here are some tips to incorporate into your conversation with patients.

Explain their risk of shingles:

- **Risk increases with age, especially after 50 years old[4,5]**
- **Shingles can be painful and lead to serious complications[4]**

SHINGRIX is not indicated for the treatment of herpes zoster or postherpetic neuralgia.

Discuss effectiveness:[1]

- **SHINGRIX was demonstrated to be >90% effective in preventing shingles in people who are 50 years or older, including those 70 to 80 years of age and older in clinical studies. SHINGRIX maintained protection for four years. The duration of protection beyond 4 years is currently under investigation.**

Tell them what to expect:

- **The specific side effects they are likely to encounter**
- **The median duration of these events**

Suggest online resources:

Patients can sign up for email, text, and phone reminders at **SHINGRIX.CA**

DID YOU KNOW?

Based on Canadian market research conducted by IPSOS in 2019, **64%** of respondents* ranked their **healthcare provider's recommendation** among the main drivers when deciding to vaccinate.[11]

At your next appointment with a patient ≥50 years of age, provide a strong recommendation for SHINGRIX vaccination!

* The sample reflects a representative sampling of n=800 Canadians aged 50 to 70 years of age who are aware of the condition of shingles and agreed to participate in the online survey.

ENGAGING WITH YOUR PATIENTS (CONT'D)

What to Expect

It's important to inform the patient:

Like all medicines, SHINGRIX can cause side effects, although not everyone gets them. Most of the side effects experienced were mild to moderate, and on average, did not last longer than 3 days. The following side effects may occur after receiving SHINGRIX:[1]

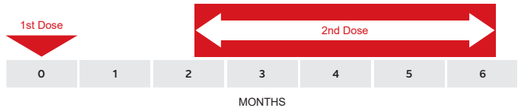
- **Very Common (these may occur with more than 1 in 10 doses of the vaccine): pain, redness and swelling at the injection site, headache, stomach and digestive complaints (including nausea, vomiting, diarrhea, and/or stomach pain), muscle pain, tiredness, chills, fever.**
- **Common (these may occur with up to 1 in 10 doses of the vaccine): injection-site itching, generally feeling unwell.**
- **Rare (these may occur with up to 1 in 1,000 doses of the vaccine): allergic reactions including rash, hives (urticaria), swelling of the face, tongue, or throat which may cause difficulty in swallowing or breathing (angioedema).**

These are not all the possible side effects you may feel when taking SHINGRIX. If any of these side effects gets serious contact your healthcare professional straightaway. If you experience any side effects not listed here, contact your healthcare professional.

VACCINATING YOUR PATIENTS WITH SHINGRIX

Dosing and Administration[1]

- SHINGRIX is a 2-dose series
- The second dose is given 2 to 6 months after the first dose
- The second dose is important to ensure maximum vaccine efficacy and duration of protection
  - The need for booster doses following the primary vaccination schedule has not been established.



Remind your patients to pre-book an appointment for their second dose of SHINGRIX.

Veeva Vault

Electronic Certificate

Version: 1 . 0

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Country: Canada

Product: SHINGRIX

Type: Promotional Material

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