SHINGRIX

HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, AS01$_B$ ADJUVANTED)

GSK

HELP PROTECT YOUR ELIGIBLE PATIENTS FROM SHINGLES WITH SHINGRIX[1]

SHINGRIX is indicated for the prevention of herpes zoster (HZ, or shingles) in adults 50 years of age or older, and in adults 18 years of age or older who are or will be at increased risk of HZ due to immunodeficiency or immunosuppression caused by known disease or therapy.[1]

DIN: 02468425

SHINGRIX DEMONSTRATED >90% EFFICACY AGAINST SHINGLES IN ALL AGE GROUPS STUDIED VS. PLACEBO[1] *




	Data from ZOE-50		Pooled data from ZOE-50 and ZOE-70	
AGE	50–59	60–69	70–79	≥80
% EFFICACY (95% CI)	**96.6%** (89.6, 99.4)	**97.4%** (90.1, 99.7)	**91.3%** (86.0, 94.9)	**91.4%** (80.2, 97.0)
SHINGLES CASES IN SHINGRIX GROUP (n)	**3** (3,492)	**2** (2,141)	**19** (6,468)	**6** (1,782)
SHINGLES CASES IN PLACEBO GROUP (n)	**87** (3,525)	**75** (2,166)	**216** (6,554)	**68** (1,792)

Adapted from SHINGRIX Product Monograph[1]

Vaccine efficacy was calculated in the **Modified Total Vaccinated Cohort (mTVC)**: All subjects randomized in the study who received a second dose of the vaccine and did not develop a confirmed case of shingles within one month after the second dose.[1]

DEMONSTRATED SUSTAINED EFFICACY AT 4 YEARS

In the fourth year after vaccination, VE against shingles in patients:

- ≥50 years was **93.1%** vs. placebo (95% CI: 81.2, 98.2).[1†]
- ≥70 years was **87.9%** vs. placebo (95% CI: 73.3, 95.4).[1‡]

CI = confidence interval; VE = vaccine efficacy.

* 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. 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). Primary endpoint was vaccine efficacy as measured by the reduction in herpes zoster risk.

† Data from ZOE-50.

‡ Pooled data from ZOE-50 and ZOE-70.

SHINGRIX SAFETY PROFILE DATA IN ADULT PATIENTS ≥50 YEARS

Solicited local and general adverse events within seven days of vaccination from ZOE-50 and ZOE-70 studies[1] * †

A subset of the total vaccinated cohort recorded with a seven-day diary card

	Aged 50–69 years		Aged ≥70 years	
Local adverse reactions‡	**SHINGRIX (%) n=2,626**	**Placebo (%) n=2,617**	**SHINGRIX (%) n=2,258**	**Placebo (%) n=2,263**
Pain	85.6	12.8	69.2	8.8
Redness	38.5	1.4	37.7	1.2
Swelling	28.5	0.9	23.0	1.1
General adverse events	**n=2,624**	**n=2,617**	**n=2,252**	**n=2,264**
Myalgia	53.0	13.2	35.1	9.9
Fatigue	51.3	18.3	36.6	14.4
Headache	45.2	18.6	29.0	11.8
Shivering	33.1	6.5	19.5	4.9
Fever§	25.9	3.2	14.3	2.7
Gastrointestinal¶	20.5	9.7	13.5	7.6

Adapted from SHINGRIX Product Monograph[1]

The majority of solicited adverse events seen with SHINGRIX were mild to moderate and were not long-lasting (median duration of three days).[1]

Pooled data on solicited local and general adverse events were collected using standardized diary cards for seven days following each vaccine dose or placebo (*i.e.*, day of vaccination and the next six days) in a subset of subjects (n=4,884 receiving SHINGRIX, n=4,880 receiving placebo with at least one documented dose in the ZOE-50 and ZOE-70 studies).

* Solicited general adverse events are those experiences which do not occur at the site of injection and are temporally associated with the use of the vaccine, whether or not considered related.

† Seven days included day of vaccination and the subsequent six days.

‡ All solicited local (injection site) adverse reactions will be considered causally related to vaccination.

§ Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route.

¶ Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

SHINGRIX DEMONSTRATED >68% EFFICACY AGAINST SHINGLES VS. PLACEBO IN TWO IMMUNOCOMPROMISED PATIENT POPULATIONS ≥18 YEARS[1] *




	auHSCT Study			Hematologic Malignancies Study
AGE	Overall (>18)†	18–49	≥50	Overall (>18)‡
% EFFICACY (95% CI)	**68.2%** (55.6, 77.5)	**71.8%** (38.8, 88.3)	**67.3%** (52.6, 77.9)	**87.2%**§ (44.2, 98.6)
SUBJECTS HAVING AT ≥1 CONFIRMED HZ EPISODE IN SHINGRIX GROUP (n)	**49** (870)	**9** (213)	**40** (657)	**2** (259)
INCIDENCE RATE OF HZ PER 1,000 PERSON-YEARS IN SHINGRIX GROUP	30.0	21.5	33.0	8.5
SUBJECTS HAVING AT ≥1 CONFIRMED HZ EPISODE IN PLACEBO GROUP (n)	**135** (851)	**29** (212)	**106** (639)	**14** (256)
INCIDENCE RATE OF HZ PER 1,000 PERSON-YEARS IN PLACEBO GROUP	94.3	76.0	100.9	66.2

Adapted from SHINGRIX Product Monograph[1]

Vaccine efficacy was calculated in the **mTVC**, defined as subjects who received two doses (0 and 1 to 2 months) of either SHINGRIX or placebo and did not develop a confirmed case of HZ within one month after the second dose.[1]

auHSCT = autologous hematopoietic stem cell transplantation; CI = confidence interval; HZ = herpes zoster; mTVC = Modified Total Vaccinated Cohort.

* Two multi-centre, randomized, observer-blind, placebo-controlled trials in subjects 18 years of age and older who received two doses of SHINGRIX or placebo at 0 and 1-2 months. Participants in ZOSTER-002 had received an auHSCT and were vaccinated 50 to 70 days post-transplant. Participants in ZOSTER-039 had hematologic malignancies and were vaccinated during or following a cancer therapy course. In the auHSCT efficacy study, subjects were followed for the development of shingles for a median of 21 months (range: 0 to 49.4 months). The primary efficacy analysis populations (mTVC) included 1,721 subjects who received two doses of either SHINGRIX or placebo and did not develop a confirmed case of shingles within one month after the second dose. In the post-hoc analysis in subjects with hematologic malignancies, subjects were followed for the development of shingles for a median of 11.1 months (range: 0 to 15.6 months). The primary efficacy analysis populations (mTVC) included 515 subjects who received two doses of either SHINGRIX or placebo and did not develop a confirmed case of shingles within one month after the second dose. The demographics of the mTVC populations were similar to the overall population in each study.[1]

† Primary study endpoint was based on confirmed HZ cases in subjects aged ≥18 years.

‡ Confirmed HZ cases in subjects aged ≥18 years was a secondary study endpoint.

§ Efficacy calculation was performed post-hoc.

SHINGRIX SAFETY PROFILE DATA FOR IMMUNOCOMPROMISED PATIENTS ≥18 YEARS

Solicited local and general adverse events within 7 days of vaccination (Total Vaccinated Cohort)[1] * †

	Aged 18–49 years		Aged ≥50 years	
Local adverse reactions	**SHINGRIX (%) n=437**	**Placebo (%) n=406**	**SHINGRIX (%) n=1,116**	**Placebo (%) n=1,080**
Pain	90	14	82	10
Redness	33	0	35	1
Swelling	22	0	18	1
General adverse events	**n=436**	**n=407**	**n=1,117**	**n=1,081**
Myalgia	61	26	50	24
Fatigue	65	42	56	39
Headache	49	27	32	20
Shivering‡	33	14	25	12
Fever	30	6	19	7
Gastrointestinal§	27	20	28	20

Adapted from SHINGRIX Product Monograph[1]

The majority of solicited adverse events seen with SHINGRIX were mild to moderate and were not long-lasting (median duration of three days).[1]

auHSCT = autologous hematopoietic stem cell transplantation.

* Seven days included day of vaccination and the subsequent six days.

† Pooled data from: ZOSTER-015 (HIV), ZOSTER-001 and ZOSTER-002 (Autologous Hematopoietic Stem Cell Transplant), ZOSTER-041 (Renal Transplant), ZOSTER-039 (Hematologic Malignancies), ZOSTER-028 (Solid Malignant Tumours). The following study groups were in the pooled analysis: SHINGRIX (three doses [Months 0, 1, and 3]), SHINGRIX (one dose of placebo at Month 0, and two doses of SHINGRIX [Months 1 and 3]), and placebo (three doses of placebo [Months 0, 1, and 3]). This is not the recommended dosing schedule. The need for booster doses following the primary vaccination schedule has not been established. Please see the Product Monograph for dosing recommendations.

‡ Shivering was not collected as a solicited general adverse reaction in auHSCT study (ZOSTER-001). In the 18 to 49-year age group: n=422 for SHINGRIX, n=403 for placebo. In the ≥50-year age group: n=1,073 for SHINGRIX, n=1,055 for placebo.

§ Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

IMPORTANT SAFETY INFORMATION

Contraindications:

- Individuals 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
- Increased risk of Guillain-Barré syndrome was observed in a post-marketing observational study in individuals 65 years of age or older within 42 days following vaccination (estimated 3 excess cases per million doses administered), with insufficient information available to determine a causal relationship with SHINGRIX

For more information:

Please consult the Product Monograph at gsk.ca/SHINGRIX/PM for important information relating to dosing and administration, adverse reactions, 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.

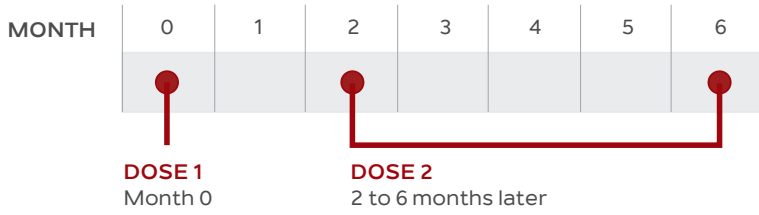
References: 1. SHINGRIX Product Monograph, GlaxoSmithKline Inc., November 15, 2022. **2.** National Advisory Committee on Immunization (NACI). Statement on the recommended use of herpes zoster vaccine. *Can Commun Dis Rep* 2010;36(ACS-1):1-19. **3.** Public Health Agency of Canada. An Advisory Committee 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. Accessed September 2022. **4.** Buchan SA *et al.* Incidence of hospitalizations and emergency department visits for herpes zoster in immunocompromised and immunocompetent adults in Ontario, Canada, 2002–2016. *Clin Infect Dis* 2020;71(1):22-29.

SHINGRIX SHOULD BE ADMINISTERED AS A TWO-DOSE SERIES[1]

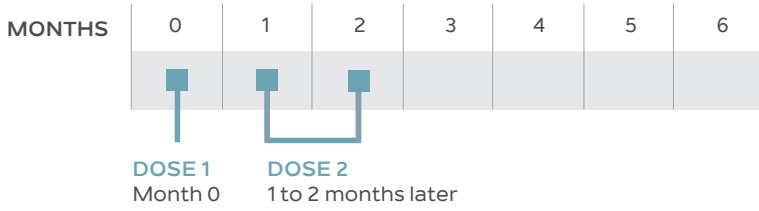
- The primary vaccination schedule consists of two doses of 0.5 mL each.
  - The initial dose at Month 0 is followed by a second dose administered anytime between two and six months later.
  - Administration of the second dose of SHINGRIX is important to ensure maximum vaccine efficacy and duration of protection against HZ disease.
  - The need for booster doses following the primary vaccination schedule has not been established.
- For individuals who are or will be immunodeficient or immunosuppressed and who would benefit from a shorter vaccination schedule, the second dose can be given one to two months after the initial dose.

Please see the Product Monograph for complete dosing and administration recommendations.

Primary vaccination schedule



Individuals who are or will be immunodeficient or immunosuppressed and who would benefit from a shorter vaccination schedule



- Schedule a follow-up immediately to administer the second dose of SHINGRIX.
- Encourage your patients to visit **SHINGRIX.ca*** to sign up to receive text or email reminders.

Vaccine storage and administration[1]

- Prior to reconstitution, the vaccine should be stored between 2°C and 8°C. Do not freeze.
- SHINGRIX is stable for 6 hours after reconstitution when refrigerated, after which it should be discarded.

- SHINGRIX is to be reconstituted only with the accompanying adjuvant suspension.

- SHINGRIX is for intramuscular (IM) injection only, preferably into the deltoid muscle.

* The Shingrix.ca web page is open to the general public.

YOUR ELIGIBLE PATIENTS COULD BE AT RISK FOR SHINGLES. RECOMMEND SHINGRIX AND HELP PROTECT THEM AGAINST SHINGLES

- **≥90% of Canadians have had varicella and are at risk for shingles.**[2]
- It has been estimated that 30% of Canadians will develop shingles at some point in their lives, increasing to almost 50% by age 85.[1]
- Age is the most important risk factor for the development of HZ, with two-thirds of the cases occurring in those over 50 years of age.[1]
- Individuals who are immunocompromised, either due to underlying conditions or immunosuppressive agents, have an increased risk of developing HZ and may be more likely to experience atypical and/or more severe disease and complications.[3]
- The **risk of hospital-attended shingles (*i.e.*, seen in hospital or emergency department) in immunocompromised adults was 2.9 times higher** than that of immunocompetent adults, and ranged from 2.6 to 12.3 times higher across types of immunocompromising conditions.[4] *

SHINGRIX is not indicated for prevention of primary varicella infection or for the treatment of herpes zoster (HZ) or postherpetic neuralgia (PHN).

Learn more at THINKSHINGRIX.CA

* According to a retrospective cohort analysis design to estimate annual incidence rates, organized by April to March fiscal year. The study included adults 18 years and older who had an emergency department visit or hospitalization for shingles from 1 April 2002 to 31 August 2016 in Ontario. Only Ontario residents with a valid provincial health insurance number were included. Ethics approval was obtained from Public Health Ontario's Ethics Research Board. The primary outcome was hospital-attended HZ (as defined by seen in hospital or emergency department).[4]

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