SHINGRIX SHOULD BE ADMINISTERED AS A 2-DOSE SERIES[1]

Recommended dosing[1]

Initial dose: 0.5mL at Month 0

2nd dose: 0.5mL anytime between 2 and 6 months later

- 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.

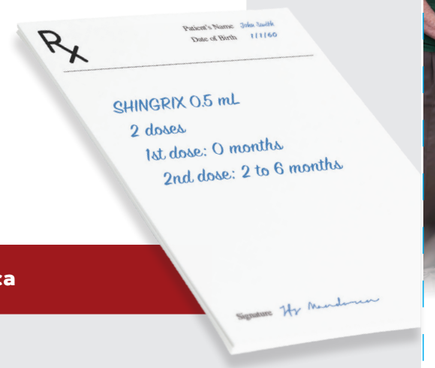
INTRODUCING SHINGRIX

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

- **SHINGRIX demonstrated:**
  - **97.2% efficacy** in patients ≥50 overall (95% CI: 93.7, 99.0; 6/7,344 vs. 210/7,415)*
  - **91.3% efficacy** in patients ≥70 overall (95% CI: 86.8, 94.5; 25/8,250 vs. 284/8,346)†
- SHINGRIX was generally well tolerated[1]
- **Non-live SHINGRIX** is for intramuscular injection, given as a 2-dose series[1]

As the risk of shingles increases, recommend SHINGRIX to help protect your patients aged 50+.

SHINGRIX
HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, AS01B ADJUVANTED)



Learn more at **ThinkSHINGRIX.ca**

* Data from ZOE-50; vaccine efficacy (VE) adjusted by age strata and region.
† Pooled data from ZOE-50 and ZOE-70; VE adjusted by age strata and region.

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INTRODUCING SHINGRIX

HELP PROTECT YOUR PATIENTS AGED 50+ FROM SHINGLES[1]

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

NOW AVAILABLE IN CANADA

DIN: 02468425

SHINGRIX
HERPES ZOSTER VACCINE (NON-LIVE RECOMBINANT, AS01B ADJUVANTED)

SHINGRIX DEMONSTRATED >90% EFFICACY AGAINST SHINGLES IN ALL AGE GROUPS STUDIED VS. PLACEBO[1,2,3*]

AGE	50–59	60–69	70–79	≥80
	Data from ZOE-50		Pooled data from ZOE-50 and ZOE-70	
% 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

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.

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

Duration of protection beyond 4 years is currently under investigation.

CI=confidence interval.

* 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 WAS GENERALLY WELL TOLERATED

Solicited local and general adverse events within 7 days of vaccination from ZOE-50 and ZOE-70 studies[1*†]

A subset of the total vaccinated cohort recorded with a 7-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

The majority of solicited adverse events seen with SHINGRIX were mild to moderate and were not long-lasting (median duration of 3 days).[1]

Pooled data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 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.

† 7 days included day of vaccination and the subsequent 6 days.

‡ 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.

IMPORTANT SAFETY INFORMATION

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
- 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%)

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.

References: 1. SHINGRIX Product Monograph, GlaxoSmithKline Inc., October 13, 2017.
2. Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, Hwang S-J, *et al.* Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. *N Engl J Med.* 2015 May;372(22):2087-96.
3. Cunningham AL, Lal H, Kovac M, Chlibek R, Hwang S-J, Diez-Domingo J, *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):1019-32.