

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR VACCINE  
PART III: PATIENT MEDICATION INFORMATION**

**SHINGRIX**

**Herpes Zoster vaccine (non-live recombinant, AS01B adjuvanted)  
Suspension for Injection**

Read this carefully before you receive **SHINGRIX**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional and ask if there is any new information about **SHINGRIX**.

**What is SHINGRIX used for?**

SHINGRIX is a vaccine that helps to protect adults against herpes zoster (also called shingles).

SHINGRIX can be given to adults 50 years and older.

**What causes Shingles?**

Shingles is caused by the same virus that causes chickenpox. After you have had chickenpox, the virus that caused it stays in your body in nerve cells. Sometimes, after many years and as you get older, the virus becomes active again and causes shingles. Anyone who has had chickenpox may get shingles and the chances of getting shingles increases as you get older. The lifetime risk of getting shingles is as high as 30% and this risk increases to almost 50% in those who live to 85 years.

**What is Shingles?**

Shingles is a serious disease that commonly results in a very painful, blistering rash. It usually occurs in one part of the body and can last for several weeks. Shingles sometimes also results in fever or headache. The pain can be severe, disabling and interfere with doing normal day-to-day activities.

If you develop shingles, it may lead to serious complications, such as long-lasting nerve pain (postherpetic neuralgia or PHN), which can last for months or years and may be severe even after the shingles blisters heal. Shingles can also lead to scarring. PHN is the most common complication you can develop if you have shingles. PHN can be serious, disabling, and can interfere with your daily activities such as walking, sleeping and social activities. The pain from shingles can also lead to emotional distress. People who suffer from shingles have described their pain in many ways. Some say the pain burns or throbs. Others say it stabs, shoots, and/or feels sharp. Severe pain can result from things as minor as a breeze or the touch of clothing against the skin. Other complications you may get with shingles can include bacterial skin infections, weakness, facial or muscle paralysis, loss of hearing or vision problems which can lead to blindness.

People with shingles may need to stay in the hospital and in rare cases shingles may even result in death.

### **How does SHINGRIX work?**

SHINGRIX helps your body to build its own protection against shingles.

SHINGRIX **does not** cause shingles. SHINGRIX is a non-live, recombinant vaccine and cannot cause the disease it is designed to prevent.

SHINGRIX was demonstrated to be more than 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.

An additional clinical study demonstrated that SHINGRIX was also effective at producing an immune response in people who previously received the live attenuated herpes zoster vaccine.

As with all vaccines, SHINGRIX may not fully protect all people who are vaccinated.

### **What are the ingredients in SHINGRIX?**

#### **Medicinal ingredients:**

1 dose (0.5 mL) contains 50 micrograms of glycoprotein E (gE) powder mixed with AS01<sub>B</sub> adjuvant suspension. gE is a protein found in the Varicella Zoster Virus. This protein is not infectious.

The adjuvant is made of 50 micrograms each of a plant extract (*Quillaja saponaria* Molina, fraction 21 (QS-21)) and a bacterial extract (3-O-desacyl-4'-monophosphoryl lipid A (MPL)) and is used to improve your body's response to the vaccine.

#### **Non-medicinal ingredients:**

Cholesterol, dipotassium phosphate, dioleoyl phosphatidylcholine, disodium phosphate anhydrous, polysorbate 80, potassium dihydrogen phosphate, sodium chloride, sodium dihydrogen phosphate dihydrate, sucrose and water for injections.

#### **SHINGRIX comes in the following dosage forms:**

0.5 mL suspension for one injection made by combining:

- One vial of gE powder
- One vial of adjuvant suspension

#### **Do not use SHINGRIX if:**

- You are allergic to any ingredient in SHINGRIX (see What are the Ingredients in SHINGRIX). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive SHINGRIX. Talk about any health conditions or problems you may have, including:**

- If you have a severe infection with a high temperature. In these cases, vaccination may be delayed until recovery. A minor infection such as a cold should not be a problem, but talk to your healthcare professional first.
- If you have a bleeding problem or bruise easily.
- If you have fainted with a previous injection or before receiving any needle injection.

**Other warnings you should know about:**

SHINGRIX is not for prevention of chickenpox or for the treatment of herpes zoster (HZ) or postherpetic neuralgia (PHN).

**Pregnancy and breast-feeding**

- Ask your healthcare professional for advice before taking any medicine.
- There is no information on the use of SHINGRIX in pregnant or breast-feeding women.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines, or if you have recently received any other vaccine.**

**Using other medicines or vaccines with SHINGRIX:**

- SHINGRIX can be given at the same time as the unadjuvanted seasonal influenza vaccine, the 23-valent pneumococcal vaccine and the combined diphtheria-tetanus-acellular pertussis vaccine. The vaccines should be given at different injection sites.

**How to receive SHINGRIX:**

- SHINGRIX is given as an injection of 0.5 mL into a muscle (usually in the upper arm).

**Usual dose:**

You will receive two SHINGRIX injections with a gap of 2 to 6 months between doses. The first injection can be given from the age of 50 years. Your healthcare professional will tell you when you should come back for the second dose.

Make sure you receive both doses of SHINGRIX. This will maximize the protection offered by SHINGRIX.

SHINGRIX can be given if you have already been vaccinated with a live attenuated herpes zoster vaccine. The appropriate time will be determined by your healthcare professional. Speak to your healthcare professional for more information.

**Overdose:**

If you think you have received too much SHINGRIX, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a scheduled injection, it is important that you make another appointment.

**What are possible side effects from using SHINGRIX?**

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:

**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.

## Reporting Suspected Side Effects

**For the general public:** Should you experience a side effect following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and GlaxoSmithKline Inc. cannot provide medical advice.

**For healthcare professionals:** If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-form-eng.php>) and send it to your local Health Unit.

## Storage:

- Keep this vaccine out of the sight and reach of children
- Store in a refrigerator (2°C to 8°C)
- Do not freeze
- Store in the original package in order to protect from light
- Do not use this vaccine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

## If you want more information about SHINGRIX:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the latest available Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website [gsk.ca](http://gsk.ca), or by calling 1-800-387-7374.

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