

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR VACCINE

SHINGRIX

Herpes Zoster vaccine (non-live recombinant, AS01_B adjuvanted) Suspension for Injection

This Patient Medication Information is written for the person who will be taking **SHINGRIX**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this vaccine. If you have more questions about this vaccine or want more information about **SHINGRIX**, talk to a healthcare professional.

What **SHINGRIX** is 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;
- adults 18 years and older who are or will be at increased risk of shingles due to immunodeficiency or immunosuppression caused by known disease or therapy.

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 chance of getting shingles increases:

- as you get older, and/or
- as factors that put you at risk of getting shingles can be different and diverse in individuals with different levels of immunosuppression (for example, underlying disease, the type, duration and combination of therapy), as well as other individual risk factors.

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.

Speak with your healthcare professional to understand what risk factors can put you at risk of getting shingles.

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, including restrictions on physical activities because of shingles-related pain, sleep, work, and affecting social interactions and emotional health.

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 SHINGRIX works:

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.

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.

In patients who had undergone autologous hematopoietic stem cell transplant and were followed for 21 months, SHINGRIX was demonstrated to be 68.2% effective in preventing shingles in people 18 years or older (71.8% in people 18 to 49 years and 67.3% in people 50 years or older). SHINGRIX also produced an immune response across different populations who are 18 years or older and at increased risk of shingles due to other immunocompromising conditions or immunosuppressive therapies.

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

The ingredients in SHINGRIX are:

Medicinal ingredients: 1 dose (0.5 mL) contains 50 micrograms of glycoprotein E (gE) powder mixed with AS01_B 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 injection.

SHINGRIX comes in the following dosage form:

0.5 mL suspension for one injection made by combining:

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

SHINGRIX will not be given to you 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 SHINGRIX is given to you. 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.
- A bleeding problem or bruise easily.
- Fainted with a previous injection or before receiving any needle injection.

Other warnings you should know about:

SHINGRIX is not for the 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.
- If SHINGRIX is given at the same time as 23-valent pneumococcal polysaccharide vaccine, you may be more likely to experience fever and/or shivering.

How to take 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. Based on your medical condition or planned treatments, your doctor may recommend that you receive the second dose 1 month after the first dose. 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, or a person you are caring for, have taken too much SHINGRIX, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

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

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 (*myalgia*)
- Tiredness
- Chills, fever

Common (these may occur with up to 1 in 10 doses of the vaccine):

- Injection site itching (*pruritus*)
- Generally feeling unwell

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- Joint pain (*arthralgia*)
- Hardness of the skin at the injection site

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*)

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine):

- Temporary inflammation of the nerves, causing pain, weakness, paralysis (Guillain-Barré syndrome)

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 right away. If you experience any side effects not listed here, contact your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada (PHAC), Health Canada (HC), 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 ([Reporting Adverse Events Following Immunization \(AEFI\) in Canada](#)) 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 Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website www.gsk.ca, or by calling the manufacturer at 1-800-387-7374.

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