

# SHINGRIX

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this vaccine, speak to your doctor or pharmacist.

### 1. Why am I receiving SHINGRIX?

SHINGRIX contains the active ingredient glycoprotein E (gE) powder mixed with AS01B adjuvant suspension. SHINGRIX is a vaccine that helps to protect adults against herpes zoster (also called shingles) as well as the long-lasting nerve pain that can follow shingles called post-herpetic neuralgia or PHN.

For more information, see Section [1. Why am I receiving SHINGRIX?](#) in the full CMI.

### 2. What should I know before I receive SHINGRIX?

You should not be given SHINGRIX if you have ever had an allergic reaction to any of the ingredients listed at the end of the CMI.

**Talk to your doctor, nurse or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I receive SHINGRIX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SHINGRIX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I receive SHINGRIX?

Your doctor or nurse will give you SHINGRIX as an injection (usually in the upper arm).

More instructions can be found in Section [4. How do I receive SHINGRIX?](#) in the full CMI.

### 5. What should I know after receiving SHINGRIX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, nurse or pharmacist you visit that you have recently received SHINGRIX.</li><li>• Keep the follow up visits with your doctor or clinic.</li><li>• Make sure you finish the complete vaccination course. This will maximise the protection offered by SHINGRIX.</li><li>• Keep a record of your immunisation history.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• There is no information on whether SHINGRIX affects the ability to drive or use machines.</li><li>• Do not drive or use machines if you are feeling unwell.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• SHINGRIX will normally be stored at the doctor's clinic or at the pharmacy.</li><li>• If you collect SHINGRIX from your pharmacy prior to the injection, store it in a refrigerator (2°C – 8°C) in the original package in order to protect from light.</li><li>• Do not freeze.</li></ul>

For more information, see Section [5. What should I know after receiving SHINGRIX?](#) in the full CMI.

### 6. Are there any side effects?

The following are very common or common side effects that may occur after receiving SHINGRIX; headache, stomach and digestive complaints, muscle pain, pain, redness and swelling at the injection site, tiredness, chills, fever, injection site itching and generally feeling unwell.

As with all vaccines given by injection there is a very small risk of serious allergic reaction. There is also a very rare risk of Guillain-Barré syndrome, resulting in temporary inflammation of the nerves, causing pain, weakness and paralysis. Contact your doctor immediately or go to the emergency department of your nearest hospital.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# SHINGRIX

**Active ingredient(s):** *Recombinant Varicella Zoster Virus glycoprotein E Vaccine*

## Consumer Medicine Information (CMI)

This leaflet provides important information about receiving SHINGRIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving SHINGRIX.**

### Where to find information in this leaflet:

- [1. Why am I receiving SHINGRIX?](#)
- [2. What should I know before I receive SHINGRIX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I receive SHINGRIX?](#)
- [5. What should I know after receiving SHINGRIX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I receiving SHINGRIX?

**SHINGRIX contains the active ingredient glycoprotein E (gE) powder mixed with AS01B adjuvant suspension.**

SHINGRIX is a vaccine.

**SHINGRIX is used to protect adults against herpes zoster (also called shingles) as well as the long-lasting nerve pain that can follow shingles called post-herpetic neuralgia or PHN.**

SHINGRIX can be given to:

- adults from the age of 50 years and above
- adults from the age of 18 years and above who are at an increased risk of shingles.

### **What is shingles and what are the complications related to shingles?**

Shingles is caused by the same virus that causes chickenpox. After you have had chickenpox (primary varicella infection), the virus that caused it stays in your body in nerve cells. Sometimes, after many years, the virus can become active again and causes shingles (secondary varicella infection).

### **SHINGRIX cannot be used to prevent chickenpox (primary varicella infection).**

Shingles is a painful, blistering rash. It usually occurs in one part of the body and can last for several weeks. It may lead to complications such as long-lasting pain (PHN) and scarring. Less commonly, bacterial skin infections, weakness, muscle paralysis, loss of hearing or vision can occur.

### **What is post-herpetic neuralgia (PHN)?**

After the shingles blisters heal, pain can last for months or years and may be severe. This long-lasting nerve pain is called post-herpetic neuralgia (PHN). PHN is the most common complication of shingles.

## How does the vaccine work?

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

SHINGRIX cannot be used to treat shingles or the pain associated with shingles. It is for the protection against shingles only.

## 2. What should I know before I receive SHINGRIX?

### **Warnings**

#### **You should not receive SHINGRIX if:**

- You are allergic to any of the ingredients listed at the end of this leaflet.

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Tell your doctor before you receive SHINGRIX if you have experienced any of these symptoms with a previous dose of SHINGRIX or any other vaccine or medicine.

#### **Check with your doctor if you:**

- currently have an infection with a high temperature. In these cases, the vaccination may be postponed until you are feeling better. A minor infection such as a cold should not be a problem, but talk to your doctor, nurse or pharmacist first.
- have any bleeding problems or bruise easily.
- fainted with any previous injections. Fainting can occur following, or even before, any needle injection.
- have been told by your doctor that you have a weakened immune system as a result of a disease, medications (including high-dose corticosteroids or cancer medicines), or other treatment.

Following vaccination, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor, nurse or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor, nurse or pharmacist if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with SHINGRIX and affect how it works.**

**Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SHINGRIX.**

### **Having other vaccines**

Tell your doctor, nurse or pharmacist if you have received another vaccine recently.

**Some vaccines may be affected by other vaccines.**

SHINGRIX can be given at the same time as:

- unadjuvanted yearly influenza (flu) vaccine
- 23-valent pneumococcal polysaccharide (PPV23) vaccine. If SHINGRIX is given at the same time as this vaccine, you may be more likely to experience fever and/or shivering.
- pneumococcal conjugate vaccine (PCV)
- reduced antigen diphtheria-tetanus-acellular pertussis (dTpa) vaccine
- coronavirus disease 2019 (COVID-19) messenger ribonucleic acid (mRNA) booster vaccine
- respiratory syncytial virus (RSV) vaccine (recombinant, adjuvanted).

If SHINGRIX is given at the same time as another vaccine, a different injection site will be used for each vaccine.

## **4. How do I receive SHINGRIX?**

Your doctor, nurse or pharmacist will give SHINGRIX as an injection.

**If you have any concerns about how this vaccine is to be given, talk to your doctor, nurse or pharmacist.**

### **How it is given**

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

### **When it is given**

- You will receive 2 injections 2 to 6 months apart. Based on your medical condition, your doctor may recommend that you receive the second injection 1 month after the first injection.
- Make sure you finish the complete vaccination course as this will maximise the protection offered by SHINGRIX.
- SHINGRIX can be given if you have previously been vaccinated with a live attenuated herpes zoster vaccine. Speak to your doctor, nurse or pharmacist for more information.

### **If a dose is missed**

If you miss a scheduled dose, talk to your doctor, nurse or pharmacist and arrange another visit as soon as possible.

**If you are not sure what to do, ask your doctor, nurse or pharmacist.**

### **If you are given too much SHINGRIX**

It is unlikely that you will be given too much SHINGRIX. However, if you think that you have been given too much SHINGRIX you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know after receiving SHINGRIX?**

### **Things you must do**

**Keep all follow up visits with your doctor or clinic. Make sure you finish the complete vaccination course. This will maximise the protection offered by SHINGRIX.**

Keep a record of your immunisation history.

Remind any doctor, nurse or pharmacist you visit that you have recently received SHINGRIX.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how SHINGRIX affects you.**

There is no information on whether SHINGRIX affects the ability to drive or use machines.

However, do not drive or use machines if you are feeling unwell.

### **Looking after your vaccine**

SHINGRIX is usually stored at the doctor's clinic or at the pharmacy.

If you need to store SHINGRIX:

- Store in a refrigerator (2°C – 8°C)
- Do not freeze.
- Keep it in the original package in order to protect from light.

Follow the instructions on the carton on how to take care of your vaccine properly.

**Keep it where young children cannot reach it.**

### **Getting rid of any unwanted vaccine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All vaccines can have side effects. If you do experience any side effects, most of them are minor and temporary.

However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor, nurse or pharmacist.

## Less serious side effects

Less serious side effects	What to do
<p><b><u>Nervous system disorders:</u></b></p> <ul style="list-style-type: none"> <li>headache</li> </ul> <p><b><u>Gastrointestinal disorders:</u></b></p> <ul style="list-style-type: none"> <li>nausea</li> <li>vomiting</li> <li>diarrhoea</li> <li>stomach pain</li> </ul> <p><b><u>Musculoskeletal and connective tissue disorders</u></b></p> <ul style="list-style-type: none"> <li>muscle pain (myalgia)</li> <li>joint pain (arthralgia)</li> </ul> <p><b><u>General disorders and administration site conditions:</u></b></p> <ul style="list-style-type: none"> <li>pain, redness, swelling at the injection site</li> <li>injection site itching (pruritus)</li> <li>tiredness</li> <li>chills</li> <li>fever</li> <li>generally feeling unwell</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b><u>Immune system disorders and allergic reactions:</u></b></p> <p>As with all vaccines given by injection there is a very small risk of serious allergic reaction. Signs of an allergic reaction are:</p> <ul style="list-style-type: none"> <li>swelling of limbs, face, eyes, inside of nose, mouth or throat</li> <li>shortness of breath, breathing or swallowing difficulties</li> <li>hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions</li> <li>unusual tiredness or weakness that is sudden and severe</li> </ul> <p>Allergy to SHINGRIX is rare (may occur with up to 1 in 1,000 doses of the vaccine). Any such severe reactions will usually occur within the first few hours after vaccination.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<p><b><u>Guillain-Barré syndrome (GBS):</u></b></p> <p>A very rare autoimmune syndrome affecting the nerves resulting in weakness of muscles.</p> <p>GBS may cause tingling of the hands or feet, or sudden numbness or weakness in the legs or arms, or problems swallowing or breathing.</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

If you are aged 50 to 69 years you are more likely to experience side effects such as pain and swelling at the injection site, fatigue, myalgia, headache, shivering, fever and gastrointestinal symptoms, compared to if you are 70 years and older.

If you are at increased risk of shingles, you are more likely to experience side effects such as pain at the injection site, fatigue, muscle pain, headache, shivering and fever if you are between the ages of 18 to 49 years, compared to if you are 50 years and older.

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://pophealth.my.site.com/carmreportnz/s/>.

By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your doctor, nurse or pharmacist before you decide to stop taking any of your medicines.

## 7. Product details

This vaccine is only available with a doctor's prescription.

### What SHINGRIX contains

<b>Active ingredient (main ingredient)</b>	<p>50 micrograms of glycoprotein E (gE) powder mixed with AS01B adjuvant suspension.</p> <p>gE is a protein present in the Varicella Zoster Virus. This protein is not infectious.</p> <p>The adjuvant is composed of a plant extract (Quillaja saponaria saponin (QS-21) (50 micrograms) and a bacterial extract (3-O-desacyl-4'-monophosphoryl lipid A (MPL) (50 micrograms)) and is used to improve the body's response to the vaccine.</p>
<b>Other ingredients (inactive ingredients)</b>	<p><b>Powder</b></p> <p>Sucrose</p> <p>Polysorbate 80</p> <p>Monobasic sodium phosphate dihydrate</p> <p>Dibasic potassium phosphate</p> <p><b>Suspension</b></p> <p>Dioleoylphosphatidylcholine</p> <p>Cholesterol</p> <p>Sodium chloride</p> <p>Dibasic sodium phosphate</p> <p>Monobasic potassium phosphate</p> <p>Water for injections</p>

**You should not be given this vaccine if you are allergic to any of these ingredients.**

### What SHINGRIX looks like

The powder is white.

The suspension is an opalescent, colourless to pale brownish liquid.

One pack of SHINGRIX consists of:

- Powder for 1 dose in a vial
- Suspension for 1 dose in a vial

SHINGRIX (TT50-10468) is available in pack sizes of:

- 1 vial of powder plus 1 vial of suspension
- 10 vials of powder plus 10 vials of suspension.

### Who distributes SHINGRIX

GlaxoSmithKline NZ Ltd  
Private Bag 106600  
Downtown  
Auckland 1143  
New Zealand

Phone: (09) 367 2900

Facsimile: (09) 367 2910

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