

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.

▼ This vaccine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given 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 being given SHINGRIX?](#) in the full CMI.

2. What should I know before I am given 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 am given 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 is SHINGRIX given?

Your doctor or nurse will give you SHINGRIX as an injection.

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

5. What should I know when being given SHINGRIX?

Things you should do	- Remind any doctor, nurse or pharmacist you visit that you have been given SHINGRIX. - Keep the follow up visits with the doctor or clinic. Make sure you finish the complete vaccination course. This will maximise the protection offered by SHINGRIX.
Things you should not do	Do not use this vaccine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
Driving or using machines	- There is no information on whether SHINGRIX affects the ability to drive or use machines. - Do not drive or use machines if you are feeling unwell.
Looking after your vaccine	- Store in a refrigerator (2°C - 8°C) in the original package in order to protect from light. - Do not freeze.

For more information, see Section [5. What should I know when being given 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. Contact your doctor immediately or go to the casualty 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.

▼ This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

SHINGRIX

Active ingredient(s): Recombinant Varicella Zoster Virus glycoprotein E Vaccine, 50 micrograms powder and 50 micrograms adjuvant suspension for suspension for injection

Consumer Medicine Information (CMI)

This leaflet provides important information about using 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 using SHINGRIX.**

Where to find information in this leaflet:

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

1. Why am I being given 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 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 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 am given SHINGRIX?

Warnings

You should not be given 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 if you have experienced any of these symptoms with a previous dose of SHINGRIX or any other vaccine or medicine.
- Always check the ingredients to make sure you can be given this vaccine.
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- if you have an infection with a high temperature. In these cases, the vaccination may be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- if you have a bleeding problem or bruise easily.
- if you fainted with a previous injection. Fainting can occur following, or even before, any needle injection.
- if you 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.
- have allergies to any other medicines, foods, preservatives or dyes.

During treatment, 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.

Your doctor, nurse or pharmacist can discuss with you the risks and benefits involved.

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 either the unadjuvanted yearly influenza (flu) vaccine, 23-valent pneumococcal polysaccharide (PPV23) vaccine* or reduced antigen diphtheria-tetanus-acellular pertussis (dTpa) vaccine. No information is available for co-administration with the adjuvanted influenza (flu) vaccine. If SHINGRIX is given at the same time as another vaccine, a different injection site will be used for each vaccine

*If SHINGRIX is given at the same time as PPV23 vaccine, you may be more likely to experience fever and/or shivering.

4. How is SHINGRIX given?

The doctor or nurse 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.
- You will be informed when you should come back for the second dose of SHINGRIX.
- Make sure you finish the complete vaccination course. This will maximise the protection offered by SHINGRIX.
- SHINGRIX can be given if you have already been vaccinated with a different herpes zoster vaccine. Speak to your doctor or nurse for more information.

If a dose is missed

If you miss a scheduled dose, talk to your doctor or nurse 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

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 13 11 26), 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 when being given SHINGRIX?

Things you must do

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

Remind any doctor, nurse or pharmacist you visit that you have been given 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:

- Keep this vaccine out of the sight and reach of children.
- Store in a refrigerator (2°C – 8°C)
- Do not freeze.
- Store in the original package in order to protect from light.

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

Keep it where young children cannot reach it.

When to discard your vaccine (as relevant)

This vaccine will not be given to you after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. Your doctor or nurse will dispose of the vaccine.

Getting rid of any unwanted vaccine

If you no longer need to use this vaccine or it is out of date, your doctor, nurse or pharmacist will be responsible for safe disposal.

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 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 or pharmacist.

Less serious side effects

Less serious side effects	What to do
<u>Nervous system disorders:</u> - headache <u>Gastrointestinal disorders:</u> - nausea - vomiting - diarrhoea - stomach pain <u>Musculoskeletal and connective tissue disorders</u> - muscle pain (myalgia) - joint pain (arthralgia) <u>General disorders and administration site conditions:</u> - pain, redness, swelling at the injection site - injection site itching (pruritus) - tiredness - chills - fever - generally feeling unwell	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<u>Immune system disorders and allergic reactions:</u> As with all vaccines given by injection there is a very small risk of serious allergic reaction. - swelling of limbs, face, eyes, inside of nose, mouth or throat - shortness of breath, breathing or swallowing difficulties - hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions - unusual tiredness or weakness that is sudden and severe 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 of vaccination. Tell your doctor or pharmacist if you notice anything that is making you feel unwell during or after a dose of vaccine	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.

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 or nurse 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 to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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

Active ingredient (main ingredient)	50 micrograms of glycoprotein E (gE) powder mixed with AS01B adjuvant suspension. gE is a protein present in the Varicella Zoster Virus. This protein is not infectious. 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.
Other ingredients (inactive ingredients)	Powder Sucrose Polysorbate 80 Monobasic sodium phosphate dihydrate Dibasic potassium phosphate Suspension Dioleoylphosphatidylcholine Cholesterol Sodium chloride Dibasic sodium phosphate Monobasic potassium phosphate Water for injections

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 is available in pack sizes of:

1 vial of powder plus 1 vial of suspension

10 vials of powder plus 10 vials of suspension.

(AUST R 289257).

Who distributes SHINGRIX

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, Victoria 3067 Australia.

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