



SCHEDULING STATUS:

S4

SHINGRIX

Herpes zoster vaccine (recombinant, adjuvanted)

Powder and suspension for suspension for injection

Contains sugar (sucrose 20 mg/0,5 mL dose)

Read all of this leaflet carefully before you/your child receive(s) this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SHINGRIX has been prescribed for you and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What SHINGRIX is and what it is used for
2. What you need to know before you receive SHINGRIX
3. How SHINGRIX is given
4. Possible side effects
5. How to store SHINGRIX
6. Contents of the pack and other further information.



1. What SHINGRIX is and what it is used for:

What SHINGRIX is used for:

SHINGRIX is a vaccine that helps to protect adults against shingles (herpes zoster) and post-herpetic neuralgia (PHN), the long-lasting nerve pain that follows shingles.

SHINGRIX is given to:

- adults 50 years and above;
- adults 18 years and above who are at increased risk of shingles.

SHINGRIX cannot be used to prevent chickenpox (varicella).

What shingles is:

- Shingles is a rash with blisters that is often painful. It usually occurs in one part of the body and can last for several weeks.
- 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, if your immune system (the body's natural defences) becomes weaker (due to age, an illness or a medicine you are taking), the virus can cause shingles.

How SHINGRIX works:

SHINGRIX reminds your body about the virus that causes shingles. This helps your immune system (the body's natural defences) stay prepared to fight the virus and protect you against shingles and its complications.

2. Before you receive SHINGRIX:

SHINGRIX should not be given:

- if you are allergic (hypersensitive) to SHINGRIX or any of the ingredients contained in



SHINGRIX (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Check with your doctor if you think any of these apply to you.

Take special care with SHINGRIX:

Your doctor needs to know before you receive SHINGRIX:

- If you have a severe 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.
- You have a bleeding problem or bruise easily.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before you receive SHINGRIX.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you fainted with a previous injection.

SHINGRIX cannot be used as a treatment if you already have shingles or shingles-related complications.

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

Talk to your doctor if you experience temporary inflammation of the nerves, causing pain, weakness, and paralysis (called Guillain-Barré syndrome) after receiving SHINGRIX. A slightly increased risk of Guillain-Barré syndrome (estimated 3 additional cases per million doses administered) has been reported in people aged 65 years and above after receiving SHINGRIX.

Other medicines and SHINGRIX:

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other



medicines, including medicines obtained without a prescription, or have recently received any other vaccine.

SHINGRIX can be given at the same time as other vaccines. A different injection site will be used for each vaccine.

You may be more likely to experience fever and/or shivering when 23-valent pneumococcal polysaccharide vaccine is given at the same time as SHINGRIX.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before being given SHINGRIX.

Driving and using machines:

SHINGRIX has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 “Possible side effects” may temporarily affect the ability to drive or use machines.

Contains sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, tell your doctor before you are given SHINGRIX.

SHINGRIX contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.



3. How SHINGRIX is given:

How SHINGRIX is given:

SHINGRIX (0,5 mL) will be given to you by a doctor or nurse. It will be injected into a muscle, usually in the upper arm.

- You will receive 2 injections 2 months apart. If flexibility in the vaccination schedule is necessary, the second dose can be administered between 2 and 6 months after the first dose.

Based on your medical condition, your doctor may also 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 live attenuated herpes zoster vaccine. Speak to your doctor for more information.

4. Possible side effects:

SHINGRIX can have side effects.

- Not all side effects reported for SHINGRIX are included in this leaflet. Should your general health worsen, or if you experience any untoward effects after being given SHINGRIX, please consult your doctor, pharmacist or other healthcare professional for advice.

Allergic reactions: If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- itchy rash of the hands and feet
- swelling of the eyes and face



- difficulty in breathing or swallowing
- sudden drop in blood pressure and loss of consciousness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SHINGRIX. You may need urgent medical attention or hospitalisation. These reactions will usually occur before leaving the doctor's surgery. However, if you get any of these symptoms you should contact a doctor urgently.

When SHINGRIX is given to you, the most common side effects that you may get are:

- pain/tenderness at the injection site, redness of the skin at the injection site, swelling of the skin at the injection site, hardness of the skin at the injection site.

The following side effects may also occur after receiving this vaccine:

Frequent side effects include:

- headache
- stomach and digestive complaints (including nausea, vomiting, diarrhoea and/or stomach pain)
- muscle pain (myalgia)
- feeling tired, chills, fever

Less frequent side effects include:

- seizures (including febrile seizures)
- itching where the injection is given (pruritus)
- generally feeling unwell

Other side effects that can occur:

- swollen glands in the neck, armpit or groin
- joint pain

Most of these side effects are mild to moderate in intensity and are not long-lasting.



Immunocompromised adults aged 18-49 years may experience more side effects compared to immunocompromised adults aged ≥ 50 years.

Adults aged 50-69 years may experience more side effects compared to adults aged ≥ 70 years.

Reporting of side effects:

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the '**6.04 Adverse Drug Reaction Reporting Form**', found online under SAHPRA's publications: <https://www.sahpra.org.za/publications/index/8>. By reporting side effects, you can help provide more information on the safety of SHINGRIX.

5. How to store SHINGRIX

Keep this medicine out of the reach of children.

Store in a refrigerator ($+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$).

Do not freeze.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information:

What SHINGRIX contains:

After reconstitution, one dose (0.5 mL) contains:

The active substances are:



Varicella Zoster Virus¹ glycoprotein E antigen^{2,3} 50 micrograms

¹ Varicella Zoster Virus = VZV

² adjuvanted with AS01B containing:

- plant extract *Quillaja saponaria* Molina,
fraction 21 (QS-21) 50 micrograms
- 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from
Salmonella Minnesota 50 micrograms

³ glycoprotein E (gE) produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology

Contains sugar (sucrose 20 mg/0,5 mL dose)

The other ingredients are:

Powder: Sucrose, polysorbate 80 (E 433), sodium dihydrogen phosphate dihydrate (E 339), dipotassium phosphate (E 340).

Suspension: Dioleoyl phosphatidylcholine (E 322), cholesterol, sodium chloride, disodium phosphate anhydrous (E 339), potassium dihydrogen phosphate (E 340) and water for injections.

What SHINGRIX looks like and contents of the pack:

One pack of SHINGRIX consists of:

- a white powder (antigen), enough for one dose, filled into transparent glass vials, sealed with grey rubber stoppers and secured with aluminium flip-off caps, fixed with coloured polypropylene tops
- a suspension (adjuvant), enough for one dose, filled into transparent glass vials, sealed with grey rubber stoppers and secured with aluminium flip-off caps, fixed with coloured



polypropylene tops. The suspension is a colourless to pale brownish liquid. The suspension is used to suspend the white powder in liquid form for injection.

The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

SHINGRIX is available in a pack size of 1 vial of powder plus 1 vial of suspension or in a pack size of 10 vials of powder plus 10 vials of suspension.

Not all pack sizes may be marketed

Instructions for use:

The following information is intended for medical or healthcare professionals only:

The powder and suspension should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not reconstitute the vaccine.

How to prepare SHINGRIX:

SHINGRIX must be reconstituted prior to administration.

1. Withdraw the entire contents of the vial containing the suspension into the syringe.
2. Add the entire contents of the syringe into the vial containing the powder.
3. Shake gently until the powder is completely dissolved.

The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not administer the vaccine.

After reconstitution, the vaccine should be used promptly; if this is not possible, the vaccine should be stored in a refrigerator (+2 °C to +8 °C). If not used within 6 hours, it should be discarded.

Before administration:

1. Withdraw the entire contents of the vial containing the reconstituted vaccine into the syringe.
2. Change the needle so that you are using a new needle to administer the vaccine.



Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Holder of Certificate of Registration:

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