Package leaflet: Information for the user

Shingrix powder and suspension for suspension for injection
Herpes zoster vaccine (recombinant, adjuvanted)

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- 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 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.

Complications related to shingles
Shingles may lead to complications.
The most common complication of shingles is:
- long-lasting nerve pain – called post-herpetic neuralgia or PHN. After the shingles blisters heal, you may get pain which can last for months or years and may be severe.

Other complications of shingles are:
- scars where the blisters have been.
- skin infections, weakness, muscle paralysis and loss of hearing or vision – these are less common.

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. What you need to know before you receive Shingrix

You must not be given Shingrix if

- you are allergic to the active substances or any of the other ingredients of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

You must not be given Shingrix if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before you receive Shingrix if:

- you have a severe infection with a high temperature (fever). In these cases, the vaccination may have to be postponed until you have recovered. 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 before or after 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 such as unadjuvanted inactivated seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine, 13-valent pneumococcal conjugate vaccine, reduced antigen diphtheria tetanus acellular pertussis vaccine, or COVID-19 mRNA vaccine. 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.

You may be more likely to experience chills, tiredness, fever, stomach and digestive complaints (including nausea, vomiting, diarrhoea and/or stomach pain), headache, muscle pain, or joint pain when a COVID-19 mRNA vaccine is given at the same time as Shingrix.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this vaccine.

Driving and using machines
Some of the effects mentioned below in section 4 "Possible side effects" may temporarily affect the ability to drive or use machines. Do not drive or use machines if you are feeling unwell.

Shingrix contains polysorbate 80, sodium and potassium
This medicine contains 0.08 mg of polysorbate 80 per dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially 'potassium-free'.

3. How Shingrix is given

- Shingrix is given as an injection 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

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Side effects reported during clinical trials and after marketing of Shingrix:

Very common (may occur with more than 1 in 10 doses of the vaccine):
- headache
- stomach and digestive complaints (including nausea, vomiting, diarrhoea and/or stomach pain)
- muscle pain (myalgia)
- pain, redness and swelling where the injection is given
- feeling tired
- chills
- fever

Common (may occur with up to 1 in 10 doses of the vaccine):
- itching where the injection is given (pruritus)
- generally feeling unwell

Uncommon (may occur with up to 1 in 100 doses of vaccine)
- swollen glands in the neck, armpit or groin
- joint pain

Rare (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)

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 any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Shingrix

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

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

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. Contents of the pack and other information

What Shingrix contains

- The active substances are:

  After reconstitution, one dose (0.5 mL) contains:
  Varicella Zoster Virus[1] glycoprotein E antigen[2] 50 micrograms

  [1] Varicella Zoster Virus = VZV
  [2] adjuvanted with $AS01_B$ 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

  The glycoprotein E is a protein present in the Varicella Zoster Virus. This protein is not infectious.

  The adjuvant ($AS01_B$) is used to improve the body's response to the vaccine.

- 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.

  See Section 2 "Shingrix contains polysorbate 80, sodium and potassium".

What Shingrix looks like and contents of the pack

Powder and suspension for suspension for injection. The powder is white.
The suspension is an opalescent, colourless to pale brownish liquid.

One pack of Shingrix consists of:
- Powder (antigen) for 1 dose in a vial
- Suspension (adjuvant) for 1 dose in a vial

Shingrix is available in a pack size of 1 vial of powder and 1 vial of suspension or in a pack size of 10 vials of powder and 10 vials of suspension.

Not all pack sizes may be marketed

Marketing Authorisation Holder
GlaxoSmithKline UK Limited
79 New Oxford Street
London
WC1A 1DG
United Kingdom

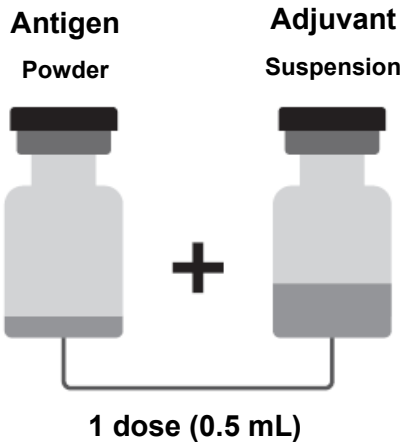
Manufacturer
GlaxoSmithKline Biologicals s.a.
Rue de l'Institut 89
B-1330 Rixensart
Belgium

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only) Please be ready to give the following information:
Product name Shingrix
Reference number 19494/0263
This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 04/2025

The following information is intended for healthcare professionals only:

Shingrix is presented as a vial with a brown flip-off cap containing the powder (antigen) and a vial with a blue-green flip-off cap containing the suspension (adjuvant).
The powder and the suspension must be reconstituted prior to administration.



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 a syringe with a suitable needle (21G to 25G).
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 – 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.