PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Shingrix

Powder and suspension for suspension for injection

After reconstitution, each dose (0.5 mL) contains:

Varicella Zoster Virus glycoprotein E (gE) antigen 50 micrograms

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Shingrix is intended for prevention of shingles [herpes zoster (HZ)] and post-herpetic neuralgia (PHN) in:

- adults 50 years of age or older;
- adults 18 years of age or older at increased risk of shingles [herpes zoster (HZ)].

The use of Shingrix should be in accordance with official recommendations.

Shingrix cannot be used to prevent chickenpox (varicella).

Therapeutic group: Herpes zoster vaccines.

What shingles (herpes zoster) 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 the nerve cells.
• Sometimes, after many years, if your immune system (the body's natural defence system) becomes weaker (due to age, an illness or medicines you are taking), the virus can cause shingles.

Complications related to shingles

Shingles may cause 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 suffer from 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 defence system) to stay prepared to fight the virus and protect you against shingles and its complications.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
• You are sensitive (allergic) to the active substance or to any of the additional ingredients contained in this medicine (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 receive Shingrix if any of the above apply to you.
If you are not sure, talk to your physician.

Special warnings regarding use of the medicine

Before you receive Shingrix, tell your physician if:

- you have a severe infection with 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 physician first.
- you have a bleeding problem or bruise easily.

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

Fainting may occur before or after any needle injection. Therefore, tell the physician 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 physician 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.

Children and adolescents

This medicine is not intended for children and adolescents below the age of 18.
There is no information about the safety and efficacy of using this medicine in children and adolescents below the age of 18.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

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 physician for advice before you are vaccinated with this vaccine.

Driving and using machines

Some of the effects mentioned below in section 4 “Side effects” may temporarily affect the ability to drive or use machines. Do not drive or use machines if you are feeling unwell.

Important information about some of the ingredients in the medicine

Shingrix contains sodium and potassium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium-free".
This medicine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially "potassium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.
The dosage and treatment regimen will be determined by the physician only.

- 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 physician may recommend that you receive the second injection 1 month after the first injection.
- You will be informed when you should come back to receive the second dose of Shingrix.

Make sure you complete the 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 physician for more information.

Do not exceed the recommended dose.
Adhere to the treatment regimen recommended by your physician.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Shingrix may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Side effects reported during clinical trials and after marketing of Shingrix

Very common side effects

These may occur with **more than 1 in 10** doses of the vaccine:

- headache
- stomach and digestive complaints (including nausea, vomiting, diarrhoea and/or abdominal [stomach] pain)
- muscle pain (myalgia)
- pain, redness and swelling at the injection site
- feeling tired
- chills
- fever

Common side effects

These may occur with **up to 1 in 10** doses of the vaccine:

- itching at the injection site (pruritus)
- generally feeling unwell

Uncommon side effects

These may occur with **up to 1 in 100** doses of the vaccine:

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

Rare side effects

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).

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 and above.

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

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store in a refrigerator (between 2°C - 8°C). Do not freeze.
- Store in the original package in order to protect from light.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:

Powder (gE antigen):

Sucrose, sodium dihydrogen phosphate dihydrate, dipotassium phosphate, polysorbate 80.

Suspension (AS01$_B$ Adjuvant System):

Sodium chloride, dioleoyl phosphatidylcholine, potassium dihydrogen phosphate, cholesterol, disodium phosphate anhydrous, 3-O-desacyl-4'-monophosphoryl lipid A (MPL), Purified Quillaja Saponin (QS-21) and water for injections.
See section 2 – "Shingrix contains sodium and potassium".

- What the medicine looks like and the contents of the package:
  - 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 contains:
  - Powder (antigen) for 1 dose in a vial
  - Suspension (adjuvant) for 1 dose in a vial

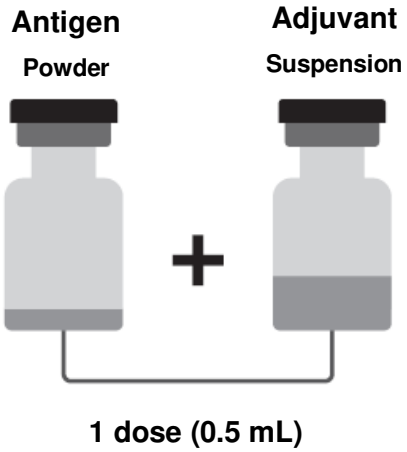
  Shingrix is available in packs of 1 vial of powder plus 1 vial of suspension or in packs of 10 vials of powder plus 10 vials of suspension.
  Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Biologicals S.A., Rixensart, Belgium.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 171-33-37389

Revised in December 2023 according to MOH guidelines.

Shingrix PT V3B

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 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 – 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.