Effects and adverse reactions of this vaccine

Shingrix is a vaccine indicated for prevention of herpes zoster in adults aged 50 years and older. Two administrations as intramuscular injection are required to receive sufficient preventive effect of Shingrix.

The major adverse reactions are injection site pain/redness/swelling with the possibility of systemic symptoms such as myalgia, fatigue and headache, however, most of the symptoms will normally be disappeared in approximately 3 days. In addition, as serious adverse reactions, shock and anaphylaxis (an allergic reaction accompanied by decreased blood pressure, difficulty in breathing or systemic urticaria appearing usually within 30 minutes after inoculation) may present.

Persons who must not undergo preventive vaccination:

1. Persons with fever (37.5℃ or higher).
2. Persons clearly suffering from an acute disease.
3. Persons who have had an anaphylactic reaction to any component of this vaccine (allergic reaction accompanied by decreased blood pressure, difficulty in breathing or systemic urticaria appearing usually within 30 minutes after inoculation).
4. In addition, persons who are judged to be unsuitable for preventive vaccination by the doctor.

Persons who must consult doctor prior to preventive vaccination:

1. Persons with an underling disease related to the cardiovascular system, kidneys, liver or blood.
2. Persons who developed fever or symptom suggestive of allergy, such as systemic rash, within 2 days after a previous preventive vaccination.
3. Persons who may be allergic to any component of this vaccine.
4. Persons with a history of convulsions (seizures).
5. Persons who have been diagnosed with immunodeficiency in the past or have a relative with congenital immunodeficiency.
6. Persons with a low platelet count or bleeding tendency.
7. Persons who are pregnant, possibly pregnant or nursing (breast feeding).
8. Persons who have had any preventive vaccination in the last month.

Post-vaccination Cautions

1. As fainting may occur after vaccination, please relax in a chair with a backrest at the vaccination facility for about 30 minutes after inoculation. Return home only after no change in physical condition has been verified.
2. Avoid strenuous exercise on the day of inoculation and keep the injection site clean. You can take a bath on the day of inoculation.
3. If you feel any abnormal reaction at the injection site or change in physical condition after inoculation or if any abnormal symptom such as a high fever occur or if you suffer from convulsions, immediately present at a clinic or hospital for an examination.
4. In the event that any adverse health effects arise as a result of inoculation with this vaccine, treatment expenses, etc. may be paid based on the “Adverse Drug Reaction Relief System”. For further details, please refer to the Pharmaceuticals and Medical Devices Agency website.

To persons desiring a herpes zoster vaccination (Shingrix for intramuscular injection):

At the time of herpes zoster vaccination (Shingrix for intramuscular injection), it is necessary to fully grasp the health status of the person to be vaccinated. Please read the explanation below, then fill in the “Inquiry form for herpes zoster vaccination (Shingrix for intramuscular injection)” and undergo a doctor’s examination. If you have difficulty filling in the form yourself, proxy can fill in.

<table>
<thead>
<tr>
<th>Scheduled Date of Vaccination</th>
<th>(dd/mm)</th>
<th>Name of Medical Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>At : am/pm</td>
<td></td>
<td></td>
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</tbody>
</table>

GlaxoSmithKline K.K.
**Screening Questionnaire for Herpes Zoster Vaccination (Shingrix)**

- **Number of Doses**: First / Second, Last Vaccination Date: / / (dd/mm/yy)
- **Address**: TEL No.
- **Patient’s Name**: M F Birth Date / / (dd/mm/yy) Age ( years)

**Questionnaire for Vaccination**

- Have you read and understood the explanation about the vaccination that will be administered today? No Yes
- Do you currently have any sort of illness? Are you feeling sick today? Yes If so, please describe in detail. No
- Have you been ill in the past month? Yes Disease name No
- Disease name
- Do you have a health problem with heart disease, kidney disease, liver disease, hematologic disease, immune deficiency, or others for which you have consulted a doctor? Where relevant, did the doctor who manages the above disease agree with today’s vaccination? Yes Disease name No
- Disease name
- Have you ever had a seizure in the past? Did you have a fever at that time? Yes At ( ) years old No
- Have you ever had a rash or urticaria (hives or ‘nettle rash’) as a reaction to medications or food, or become ill after eating certain foods or receiving certain medications? Yes Food or medication name No
- Food or medication name
- Have any of your family members or relatives had a serious reaction to a vaccine in the past? Yes Vaccine name No
- Vaccine name
- Do you have a family member or relative with a congenital immunodeficiency? Yes No
- Have any of your family or anyone around you contracted measles, rubella, chickenpox, or mumps in the past month? Yes Disease name No
- Disease name
- Have you been vaccinated in the past month? Yes Vaccine name ( ) Date administered: / / (dd/mm/mm)
- Have you had a serious reaction to a vaccine in the past? Yes Vaccine name No
- Have you had a fever at that time? No
- (Women only) Are you pregnant or possibly pregnant? Are you nursing (breast feeding)? Yes Yes No No
- Do you have any questions about today’s vaccination? Yes Describe in specific No

**Doctor’s Comment**

Based on the above answers and the results of interview, I have decided that the patient (can / should not) receive a vaccination today. I have explained to the patient (or proxy) the information concerning the benefits and side effects of vaccination as well as the Relief System for Sufferers from Adverse Drug Reactions.

Signature or Name and Seal of Doctor: __________________________

Having interviewed and explained by the doctor, do you wish to receive a vaccination with the understanding of the benefits and side effects of vaccination and the Relief System for Sufferers from Adverse Drug Reactions? Yes / No

Signature of the Patient or Proxy: __________________________

If proxy signs, describe relationship __________________________

**Vaccine Name**: Freeze-dried recombinant herpes zoster vaccine (prepared from Chinese Hamster Ovary Cells)

**Vaccination Site, Dosage, and Administration**: Intramuscular injection, 0.5 ML (R / L)

**Institution, Doctor Name, Date Administered**

- Lot No.:________________________
- Institution
- Date: / / (dd/mm/yy)
- Administered At: am / pm

This screening questionnaire is used to ensure the safety of vaccination. The personal information described here will be used only for screening for vaccination.

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