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SCIENCE MEDICINES HEALTH

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Shingrix (*herpes zoster vaccine, recombinant, adjuvanted*)

An overview of Shingrix and why it is authorised in the EU

What is Shingrix and what is it used for?

Shingrix is a vaccine used in adults aged 50 years and over to protect against shingles (herpes zoster) and post-herpetic neuralgia (long-lasting nerve pain following shingles). It can also be used from the age of 18 years and over in adults who are at increased risk of herpes zoster.

Shingles is a painful, blistering rash caused by the reactivation of the virus that causes chickenpox. After a patient has had chickenpox, the virus can lie dormant in the nerves and become active again if the immune system (the body's natural defences) weakens due, for example, to ageing or to an illness.

Shingrix contains a protein (glycoprotein E) from varicella zoster virus, the virus that causes chickenpox.

How is Shingrix used?

Shingrix can only be obtained with a prescription and should be used according to official recommendations. It is available as a powder and a suspension to be mixed together by a doctor or a nurse before being injected into the upper arm muscle.

The vaccination course consists of 2 injections given 2 months apart. If necessary, the second dose can be given later but within 6 months after the first dose. People whose immune system does not work properly and who would benefit from a shorter vaccination schedule can have the second dose one to two months after the first dose.

For more information about using Shingrix, see the package leaflet or contact your doctor or pharmacist.

How does Shingrix work?

Shingrix has been designed to prevent shingles in people who have been in contact with the varicella zoster virus and have already developed antibodies against the virus.

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Shingrix contains small amounts of a surface antigen (protein from the surface) of the virus to stimulate the body to make antibodies against the virus. It also contains an 'adjuvant' which is made of substances to help strengthen the immune responses to the vaccine.

Patients given Shingrix will be able to produce antibodies against the virus more quickly when the virus is reactivated and they will therefore have protection against the disease.

What benefits of Shingrix have been shown in studies?

Shingrix has been shown in two main studies to be effective at preventing shingles and post-herpetic neuralgia in patients 50 years and older.

In the first study, 7,695 received Shingrix and 7,710 received placebo (a dummy treatment). After just over 3 years on average, 6 adults had had shingles in the Shingrix group compared with 210 in the placebo group. After almost 4 years, nobody had had post-herpetic neuralgia in the Shingrix group compared with 18 in the placebo group. This indicates that Shingrix prevented 97% of shingles cases and 100% of cases of post-herpetic neuralgia in this study.

The second study involved adults aged 70 and over who received either Shingrix or placebo. Looking at the results for adults in this age group from both studies together, 25 adults out of 8,250 who received Shingrix had shingles within 4 years after vaccination compared with 284 out of 8,346 who received placebo. After 4 years, 4 adults had had post-herpetic neuralgia in the Shingrix group compared with 36 in the placebo group. This indicates that Shingrix prevented 91% of shingles cases and 89% of cases of post-herpetic neuralgia in adults aged 70 years and older.

Shingrix was also effective in two studies in adults aged 18 years and above at increased risk of developing herpes zoster. In the first study, involving people who had received an autologous (from the patient's own body) stem cell transplant, the number of people who had herpes zoster was 49 (out of 870) in the Shingrix group compared with 135 (out of 851) in the placebo group; in the second study, involving patients with blood cancer, these figures were 2 (out of 259 people) and 14 (out of 256), respectively. These studies indicate that Shingrix prevented 68% and 87% of cases, respectively.

What are the risks associated with Shingrix?

The most common side effects with Shingrix (which may affect more than 1 in 10 people) are reactions at the site of injection (such as pain, redness and swelling), chills, fever, muscle pain, tiredness, headache and side effects of the digestive system such as nausea, vomiting, diarrhoea and stomach pain. Most of these reactions last for 2 to 3 days.

For the full list of side effects and restrictions with Shingrix, see the package leaflet.

Why is Shingrix authorised in the EU?

Shingrix has been shown to be highly effective at preventing shingles and post-herpetic neuralgia in adults older than 50 years for at least 4 years after vaccination. The vaccine is also effective at protecting adults older than 18 years who are at increased risk of herpes zoster. Side effects related to the use of Shingrix seemed to be mostly temporary and were manageable with standard care.

The European Medicines Agency therefore decided that Shingrix's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Shingrix?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Shingrix have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Shingrix is continuously monitored. Side effects reported with Shingrix are carefully evaluated and any necessary action taken to protect patients.

Other information about Shingrix

Shingrix received a marketing authorisation valid throughout the EU on 21 March 2018.

Further information on Shingrix can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](https://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports).

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