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## Background

In 2010, the Joint Committee on Vaccination and Immunisation (JCVI) was asked by the Secretary of State for Health to review all the available evidence relevant to offering a universal vaccination programme for shingles. The JCVI reviewed evidence on the disease epidemiology, vaccine efficacy and safety and cost effectiveness of introducing a routine shingles vaccination programme in the UK. The JCVI concluded that the incidence of shingles increases with age, with the severity and disease burden increasing as the individual gets older. Based on the findings of the cost-effectiveness analysis, the JCVI recommended a universal routine herpes zoster (shingles) vaccination programme for adults aged 70 years, with a catch-up programme for those aged 71 to 79 years, which commenced in September 2013.

The aim of the universal vaccination programme is to reduce the incidence and severity of shingles disease in older people.

In February 2018, the JCVI recommended that the Shingrix<sup>®</sup> inactivated shingles vaccine should be offered to all immunocompromised (immunosuppressed) individuals for whom Zostavax<sup>®</sup> is contraindicated but who are eligible for vaccination under the current programme, so that they can gain a similar level of protection to those who are not immunocompromised. The committee noted that vaccination in this group was particularly important, due to the higher incidence of herpes zoster. This advice was consistent with the original recommendation for vaccination of all adults aged 71 to 79 years with herpes zoster vaccine. At this time, there were insufficient supplies of Shingrix<sup>®</sup> vaccine to be able to implement this recommendation.

From September 2021, Shingrix<sup>®</sup> vaccine was

available as an alternative shingles vaccine for use in patients where Zostavax<sup>®</sup> is clinically contraindicated.

From 1 September 2023, all newly eligible individuals will be offered two doses of the non-live shingles vaccine Shingrix<sup>®</sup> instead of a single dose of Zostavax<sup>®</sup>. In addition to this, the eligibility for the immunosuppressed and immunocompetent cohorts will change to allow individuals to be protected at an earlier age.

Shingles vaccine is available through GP surgeries in primary care, and GPs are encouraged to identify and offer the shingles vaccination to eligible patients.

Any individual who reaches their 80th birthday is no longer eligible for a shingles vaccination due to the reducing efficacy of the vaccine as age increases. This reflects the recommendation made by JCVI in 2010.

## What is shingles?

Shingles is a viral infection of the nerve cells that develops as a result of a chickenpox infection (varicella zoster). Once a person has recovered from chickenpox, the varicella zoster virus lies dormant in the nerve cells and can reactivate at a later stage when the immune system is weakened. Reactivation of the virus is thought to be associated with immunosuppression as a result of a decline in cell mediated immunity due to old age, immunosuppressant therapy or HIV infection.

## Who does it affect?

Shingles can develop at any time following a chickenpox infection and can occur in individuals of any age. However, risk and severity of shingles increases with age. Thus, the burden of disease among adults aged 70 and above is considerably greater than younger adults.

Individuals in this age group can experience a severe form of the disease often resulting in secondary complications such as post herpetic neuralgia (PHN) and secondary bacterial skin infections that may require hospitalisation.

## The shingles vaccination programme

### What is the purpose of the programme?

The aim of the Northern Ireland shingles immunisation programme is to reduce the incidence and severity of shingles disease and subsequent PHN. Although shingles can occur at any age, the risk and severity of shingles and its complications increases with age and is high in individuals who are severely immunosuppressed. The programme is designed to ensure that those at greatest risk are vaccinated at an earlier age.

### Key changes from September 2023

Shingrix® will replace Zostavax® for all new eligible cohorts included in the programme.

Shingrix® will require a two-dose schedule for all cohorts. The dosing interval will differ for immunosuppressed and immunocompetent patients.

Shingrix® should be offered to all people who are the eligible age on 1 September 2024.

Those cohorts previously eligible for Zostavax® (those currently aged 71 to 79 years of age) who are under 80 years of age should be offered Shingrix®.

## Vaccine eligibility from 1 September 2023

Vaccine from programme stocks MUST only be used for the defined age cohorts, because of vaccine supply constraints. Use will be carefully

monitored to ensure there is adequate supply for the programme.

### Severely immunosuppressed individuals

From 1 September 2023, severely immunosuppressed individuals (eligibility as defined in the Green Book Shingles chapter 28a) aged 50 years and over who have not received the shingles vaccine before will be eligible for two doses of the Shingrix® vaccine. The second dose should be given 8 weeks to 6 months after the first dose for this cohort. There is no upper age limit but individuals should be offered the vaccine as soon as they become eligible to provide protection as early as possible.

Severely immunosuppressed individuals represent the highest priority for vaccination given their risk of severe disease and therefore the programme aims to catch up all severely immunosuppressed individuals aged 50 years and over in the first year of the programme implementation. For full details and summary of individuals and conditions where Shingrix® should be offered at 50 years of age refer to the 'Definition of severe immunosuppression' section in the Green Book Shingles chapter 28a. The decision should be based on a clinical assessment and, where appropriate, discussion with the individual patient's treating physician.

### Immunocompetent individuals

The eligible age for immunocompetent individuals will change from 70 to 60 years of age for the routine cohort, in a phased implementation over a 10-year period. The routine offer will move from 70 to 60 years of age in two stages over a 10-year period.

During stage 1 (1 September 2023 to 31 August 2028) Shingrix® will be offered to those who are **aged 70 and 65 years on 1 September 2023** (and each year up to 2028).

During stage 2 (1 September 2028 to 31 August 2033) Shingrix® will be offered to those **aged 65 and 60 years of age on 1 September 2028** (and each year up to 2033).

From 1 September 2033 and thereafter, Shingrix® will be offered routinely at age 60 years.

Implementation stages	Delivery period	Eligible for first dose
Stage 1 (5-year duration)	1 Sept 2023 to 31 Aug 2028	Those who are aged 65 or 70 on 1 September should be called to receive both doses during this delivery period.*
Stage 2 (5-year duration)	1 Sept 2028 to 31 Aug 2033	Those who are aged 65 or 60 on 1 September should be called to receive both doses during this delivery period.*
Ongoing routine offer	1 Sept 2033 onwards	Those aged 60 on 1 September should be called in during this programme year.*

\* those that become eligible but do not take up the vaccine offer immediately remain eligible until their 80th birthday. Individuals who were eligible for Zostavax® prior to September 2023 can receive two doses of Shingrix®.

### Eligibility for Shingrix® vaccine on the routine immunisation programme

Eligible cohorts	Age	Number of doses	Schedule: Two doses a minimum of 8 weeks apart
Individuals who are severely immunosuppressed (eligibility as defined in the Green Book Shingles chapter 28a)	From 50 years of age [see note 1].	2 doses	0 and 8 weeks to 6 months
Immunocompetent individuals who have not previously received shingles vaccine	All 71 to 79 years of age (already eligible).  Those who are aged 65 and 70 years of age on 1 September 2024 (and then aged 65 and 70 years of age on 1 September in subsequent years) [see note 2].	2 doses	0 and 6 to 12 months

Notes:

1. Individuals who are severely immunosuppressed remain eligible with no upper age limit but should be offered a vaccine as soon as they become eligible by age. They should be offered the second dose of vaccine after 8 weeks to ensure they are protected as early as possible.
2. Immunocompetent individuals remain eligible until their 80th birthday; the second dose should be completed before the 81st birthday. The second dose should be offered at 6 months to 12 months.

## What is the recommended vaccine for the programme?

There is one shingles vaccine currently available for use within the national programme:

- Shingrix®: a non-live recombinant sub-unit vaccine given as a two-dose schedule for all newly eligible cohorts

### Prescription only medicines

Shingrix® is a prescription-only medicine and must be administered using a prescription, Patient Group Direction (PGD) or Patient Specific Direction (PSD). The Strategic Planning and Performance Group (SPPG) in collaboration with the Public Health Agency (PHA) have developed a PGD template for Shingrix® to support the delivery of the shingles vaccine programme.

### Vaccine storage

Shingrix® should be stored in a vaccine refrigerator between +2°C and +8°C. The vaccines should be stored in the original packaging to protect them from light.

Further information on vaccine storage is available in the Summary of product characteristics (SPC)

Shingrix®, the Patient Group Direction and from the manufacturer.

## Shingrix® vaccine

Shingrix® is a non-live recombinant adjuvanted subunit shingles vaccine. It does not contain any live virus. Shingrix® contains a single protein glycoprotein E (gE) found in the outer shell of the herpes zoster virus, and an adjuvant AS01B to enhance the body's immune response to the antigen. By combining the varicella zoster virus (VZV) specific antigen (gE) with the AS01B adjuvant, Shingrix® is designed to induce antigen-specific cellular and humoral immune responses in individuals with pre-existing immunity against VZV.

Shingrix® does not contain latex, thiomersal or gelatine.

The Shingrix® vaccine was approved for use in adults 50 years of age or over in the US, Canada and Australia in 2017, and for use in the European Union and Japan in 2018. It is also licensed for use in the UK, New Zealand, Singapore and China. Current usage of Shingrix® has been related to the availability and supply of the vaccine in different countries.

For the full list of vaccine components and excipients, refer to the manufacturer's Summary of product characteristics (SPC).

## What is the efficacy of Shingrix® in adults aged 70 years and above?

In the phase 3 randomised placebo controlled clinical trials of 15,411 participants, vaccine efficacy in the 6,950 immunocompetent adults aged 70 years, administered with two doses of Shingrix® two months apart was estimated at 91.2%.

### Shingrix®: contraindications and precautions

The contraindications and precautions to Shingrix® are:

- systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of Shingrix® vaccine or any component (excipient) of Shingrix®.

Immunisation of individuals who are acutely unwell should be postponed until they have recovered fully. This is to avoid confusing the diagnosis of any acute illness by wrongly attributing any sign or symptoms to the adverse effects of the vaccine.

For full details refer to the Green Book Shingles chapter 28a and Shingrix® PGD.

### Shingrix®: presentation

Shingrix® is available as a white powder for reconstitution with diluent and is injected as a suspension. After reconstitution, the suspension 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. The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, the vaccine should not be administered. 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 six hours, discard.

### Shingrix®: administration

Shingrix® should be given by intramuscular injection, preferably in the deltoid region of upper arm. Shingrix® should not be administered intravascularly or intradermally. Subcutaneous administration is not recommended.

Shingrix® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects.

Intramuscular injections should be given with the needle at a 90-degree angle to the skin and the skin should be stretched to aid dispersal of subcutaneous tissue. It is not necessary to aspirate the syringe after the needle is introduced into the tissue.

### Shingrix®: dosage and schedule

Eligible individuals should receive two doses of 0.5mL of Shingrix® a minimum of 2 months apart for those who are immunosuppressed, and a minimum of 6 months apart for those who are immunocompetent.

### Vaccination of individuals with a bleeding disorder

Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication or treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or treatment is administered.

Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled international normalised ratio (INR) testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least two minutes.

If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. On occasion the treating clinician may conclude, in discussion with the patient, that the benefit of protection against shingles could outweigh the increased risk of a transient local reaction with intramuscular immunisation. Subcutaneous administration is off-label and a prescription or Patient Specific Direction (PSD) would be required.

The individual or carer should be informed about the risk of haematoma from the injection.

## Adverse effects

### Shingrix®

The most commonly reported side effects were pain at injection site, myalgia, fever headache, fatigue, and gastrointestinal upset. These were mostly short-lived with a median duration of 2-3 days.

A full list of side effects can be found in the Shingrix® summary of product characteristics.

### Development of a rash after Shingrix® vaccine

As Shingrix® vaccine is not a live vaccine, it should not cause the development of a vesicular rash. If a vesicular rash does develop after Shingrix® vaccine, the patient should be referred for prompt assessment and management as it is likely that they have developed shingles naturally (not due to the vaccine) and are at risk of disseminated zoster.

### Reporting adverse reactions to Shingrix® vaccine

Serious suspected adverse reactions to Shingrix® should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the yellow card reporting scheme.

## Can Shingrix® be given at the same time as other vaccines?

In line with general advice about co-administration of inactivated or non-live vaccines, Shingrix® can be given concomitantly with inactivated influenza vaccine. Initially, a seven day interval was recommended between Shingrix® and adjuvanted influenza vaccine because the potential reactogenicity from two adjuvanted vaccines may reduce tolerability in those being vaccinated. Interim data from a US study on co-administration of Shingrix® with adjuvanted seasonal influenza vaccine is reassuring. Therefore, an appointment for administration of the seasonal influenza vaccine can be an opportunity to also provide shingles vaccine, although the latter should be offered all year round, rather than purely as a seasonal programme.

Shingrix® can also be given concomitantly with the 23-valent pneumococcal polysaccharide vaccine (PPV23). In phase III controlled open label clinical studies of Shingrix® in adults aged 50 years and older, individuals received PPV-23 with their first dose of Shingrix®. The immune responses of the co-administered vaccines were unaffected, although fever and shivering were more commonly reported when PPV-23 was given with Shingrix®.

As Shingrix® is a non-live vaccine, where individuals in an eligible cohort present having recently received another inactivated or live vaccine, Shingrix® vaccination should still be offered. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.



## Recommendations for the use of shingles vaccines

### Definition of severe immunosuppression

For details about which conditions and medications or therapies indicate that an individual is severely immunosuppressed, and should be offered the Shingrix® vaccine from 50 years of age, immunisers should refer to the Green Book Shingles chapter 28a. The decision should be based on a clinical assessment and, where appropriate, discussion with the patient's treating physician.

### Patients receiving antiviral agents (oral or intravenous)

The response to the Shingrix® vaccine will not be affected by current receipt of oral or intravenous antivirals.

The use of topical aciclovir is not a contraindication to Shingrix® vaccination.

### Topical or inhaled corticosteroids or corticosteroid replacement therapy

Shingrix® is not contraindicated for use in individuals who are receiving topical or inhaled corticosteroids or corticosteroid replacement therapy.

### Anticipating immunosuppressive therapy

The risk and severity of shingles is considerably higher among severely immunosuppressed individuals and therefore individuals from 50 years of age anticipating immunosuppressive therapy should ideally be assessed for vaccine eligibility and offered a shingles vaccine before starting treatment. Eligible individuals who have not previously been vaccinated should commence a course of Shingrix® at the earliest opportunity and ideally at least 14 days before starting immunosuppressive therapy, although leaving one month would be preferable if a delay is possible.

### Individuals aged 18 to 49 years of age receiving stem cell transplant

Individuals who have received a stem cell transplant have an increased risk of developing herpes zoster which may have severe and debilitating effects. In recognition of this, it is reasonable to give adult stem cell transplant recipients who are not otherwise eligible two doses of Shingrix® vaccine as part of their overall treatment plan. This includes adult recipients of allogeneic transplant, autologous transplant or a CAR-T (chimeric antigen receptor T-Cell) therapy. Refer to the Green Book Shingles chapter 28a for full details.

### Patients 80 years of age and above

The Shingrix® vaccine is available via the routine immunisation programme for immunocompetent individuals up to the 80th birthday. Where an individual has turned 80 years of age following their first dose of Shingrix®, a second dose should be provided to complete the two-dose schedule. Immunocompetent individuals will no longer be eligible to receive the second dose once they have reached their 81st birthday.

For severely immunosuppressed individuals there is no upper age limit for starting or completing the two-dose course but individuals should be offered the vaccine as soon as they become eligible to provide protection as early as possible.

## Vaccination and previous history of infection

### If an individual does not have a previous history of chickenpox, should they still be offered the vaccine?

A previous clinical history of chickenpox infection is not a pre-requisite for receiving Shingrix®. Although an individual may present without a clinical history of chickenpox, the majority of

adults in the UK are immune and many would have had a subclinical infection without being aware. The vaccine should therefore still be offered to individuals without a clinical history of chickenpox to ensure protection against shingles. Individuals who have been tested for chickenpox and are negative for varicella zoster (VZV) on a quantitative test should not be offered shingles vaccine but should be assessed on an individual basis to decide on the best course of action.

### Vaccination of individuals with a recent chickenpox infection

Individuals presenting with a recent chickenpox infection should be offered the Shingrix® vaccine when they have fully recovered.

### Interval after exposure to a person with chickenpox or shingles

Shingrix® vaccine can still be offered if an individual has been exposed to another person with chickenpox or shingles without any interval providing the patient is well and there are no known contraindications to the vaccine. Shingrix® is not recommended for use as post-exposure prophylaxis for chickenpox.

### Individuals with a recent history of shingles

Individuals with a previous history of a shingles infection are still eligible for a shingles vaccine.

The shingles vaccine can be given at any time following natural infection. As long as the individual is eligible, has recovered from acute infection and has no active vesicles, there is no additional wait period.

### Recurrent shingles

Patients who have two or more episodes of shingles in one year should have immunological investigation prior to vaccination. Clinicians may wish to discuss such cases with local specialist teams.

### Individuals with post herpetic neuralgia or residual nerve pain

The shingles vaccine is not licensed or recommended for the treatment of shingles or shingles related postherpetic neuralgia (PHN).

As PHN can persist for many months or years, if the patient is eligible for the shingles vaccine by age and they have no other symptoms, then the recommendation would be to offer the shingles vaccine without any specific interval before offering the vaccine.

### Individuals given Zostavax® before 60 years of age

Immunocompetent and mildly immunosuppressed individuals given Zostavax® before 60 years of age should be offered the Shingrix® vaccine once they reach the eligible age for shingles vaccine via the national programme, leaving an interval of five years since the last dose of Zostavax® vaccine.

Severely immunosuppressed individuals (definition in the Green Book Shingles chapter 28a) who were given Zostavax®, for example pre-immunosuppressive treatment, and before 50 years of age, should be given the Shingrix® vaccine when they reach the eligible age for the vaccine on the national programme. There is no reason to leave any interval after a previous Zostavax® vaccine for this group.

### Immunocompetent individuals given Zostavax® between 60 and 70 years of age

Immunocompetent individuals who received a dose of Zostavax® between 60 and 70 years of age should be assessed on an individual basis for recommendation on further doses of shingles vaccine when they reach the eligible age for the shingles vaccine on the national programme.

### **Vaccination of individuals who have received Shingrix® before**

If two doses of the Shingrix® vaccine have been administered, with an interval of at least 8 weeks, no further vaccine is required for either immunocompetent or individuals with severe immunosuppression. This would be regardless of the number of years since the administration of the Shingrix® vaccine or the age at which they received these doses. At present, there is no recommendation to give a booster dose after the primary schedule has been completed.

If a single dose of Shingrix® vaccine has been given to a severely immunosuppressed individual over 50 years of age then a second dose of Shingrix® vaccine should be given with a minimum interval of 8 weeks to complete the two-dose course, regardless of the interval between doses. The course does not need to be restarted.

If an immunocompetent healthy individual has received a single dose of the Shingrix® vaccine, then they should wait until they reach the eligible age for the Shingrix® vaccine via the national programme and then be offered a second dose to complete the course for full protection. Where the course of immunisation is interrupted, there is no need to restart the course.

### **Individuals who received Zostavax® as part of the previous routine programme**

Individuals who received Zostavax® previously on the routine immunisation programme (who are now 71 to 79 years of age) are not eligible for additional doses of shingles vaccine and should not be revaccinated or offered Shingrix® now.

The need for, and the timing of a booster dose has not yet been determined. Therefore, no booster dose is currently recommended.

### **Previous incomplete course of Shingrix® vaccine**

If the course of the Shingrix® vaccine is interrupted or delayed it should be resumed as soon as possible to provide protection. The first dose does not need to be repeated.

### **What if the second dose of Shingrix® vaccine is given early?**

The recommended schedule for the Shingrix® vaccine is two doses, with the second dose given a minimum of 8 weeks after the first dose. Only if the second dose is given earlier than 4 weeks from the first dose then the dose should be repeated with an interval of at least 8 weeks from the last dose.

### **Patients eligible for shingles vaccine (71 to 79 years of age) for whom Zostavax® had been previously contraindicated**

Patients between 71 and 79 years of age who were not given shingles vaccination previously because it was contraindicated due to an underlying medical condition or treatment, should be re-assessed and offered Shingrix® if suitable.

### **Inadvertent vaccine administration errors**

Where there are errors in vaccine administration, health professionals should report these via their local governance system so appropriate action can be taken. This way lessons may be learnt and the risk of repeat errors will be reduced.

### **Inadvertent administration of Shingrix® during pregnancy**

There are no data on the use of Shingrix® in pregnant women but as a precautionary measure it is preferable to avoid the use of Shingrix® during pregnancy. If Shingrix® vaccine is inadvertently administered to a pregnant woman, the individual should be informed and reassured that there is no

known risk associated with giving Shingrix® during pregnancy since as it is an inactivated vaccine, it cannot replicate and therefore cannot cause infection in the mother or foetus. They should be advised to seek medical advice for any concerns.

#### **Inadvertent administration of Shingrix® to a child**

Shingrix® is licensed from 18 years of age. Parents should be advised of the error and of possible side effects such as pain at the injection site, fatigue, myalgia, headache, fever, and to seek medical advice with any concerns. If Shingrix® was inadvertently given to a child instead of varicella vaccine, the dose does not count and varicella vaccine should be administered as soon as possible after the error is realised. There is no recommended interval between inadvertent Shingrix® vaccine and varicella vaccine.

#### **Incomplete dose given**

If an incomplete dose of Shingrix® has been given inadvertently, this dose should be discounted.

If the patient is still in the clinic, administer a replacement full dose immediately. If the replacement dose cannot be given on the same day, administer it four weeks after the invalid (incomplete or partial) dose. This interval is necessary because of potential reactogenicity.

If this was an incomplete first dose of Shingrix®, the completing dose should be given at the appropriate interval after the replacement dose (8 weeks for a severely immunosuppressed individual and 8 weeks to 12 months (according to local operational guidance) for immunocompetent individuals).

#### **Inadvertent administration of Shingrix® suspension only**

As the suspension contains AS01B adjuvant system which can be highly reactogenic, it is recommended that an interval of four weeks is observed before giving the correctly reconstituted dose. If the Shingrix® vaccine is being offered prior to immunosuppressive treatment then a risk assessment should be carried out on an individual patient basis for timings on giving the correctly reconstituted dose.

#### **Inadvertent administration of varicella vaccine (Varivax or Varilrix) to an adult instead of Shingrix®**

Immunosuppressed individuals who are inadvertently vaccinated with live varicella vaccine (Varivax or Varilrix) when they should have received inactivated shingles vaccine (Shingrix®) should be urgently assessed to establish the degree of immunosuppression and followed up on an individual basis.

## Further resources

The Green Book: Chapter 28a Shingles (Herpes Zoster)

<https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a>

UKHSA shingles vaccine information

<https://www.gov.uk/government/collections/shingles-vaccination-programme>

nidirect information on shingles

<https://www.nidirect.gov.uk/conditions/shingles>

The use of human and animal products in vaccines

<https://www.gov.uk/government/publications/use-of-human-and-animal-products-in-vaccines>

Viral Rash in Pregnancy Guidelines

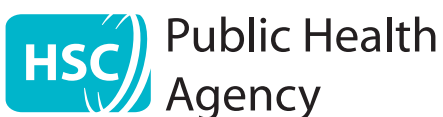
<https://www.gov.uk/government/publications/viral-rash-in-pregnancy>

NICE information on Varicella-zoster immunoglobulin

<https://bnf.nice.org.uk/drugs/varicella-zoster-immunoglobulin/>

The shingles vaccine - to help protect you from the pain of shingles

<https://www.publichealth.hscni.net/publications/shingles-vaccine-help-protect-you-pain-shingles>



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