



Public Health  
England

Protecting and improving the nation's health

# **Vaccination against shingles: 2015/16**

## **Information for healthcare professionals**

# About Public Health England

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## Executive summary

From the 1<sup>st</sup> September 2013, a national vaccination programme against shingles (herpes zoster) was introduced for older adults. This guidance document was first published in 2013 to support healthcare professionals in the implementation of the shingles vaccine programme in England.

In response to a large number of clinical enquiries regarding the use of the live attenuated shingles vaccine in specific clinical risk groups, the Immunisation department at Public Health England has convened an expert working group\* to review the available evidence and liaise with international colleagues to update the guidance.

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## Background

In 2010, the Joint Committee on Vaccination and Immunisation (JCVI)<sup>1</sup> was asked by the Secretary of State for Health to review all the available evidence relevant to the introduction of a universal vaccination programme to protect against shingles (Herpes Zoster).

The JCVI considered a range of issues including disease epidemiology, vaccine efficacy and safety and cost effectiveness of introducing a routine shingles vaccination programme in the UK. 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 71-79 years.

The aim of the universal vaccination programme is to reduce the incidence and severity of shingles disease in older adults where the risk and severity of disease is higher.

### What is shingles?

Shingles is a viral infection of the nerve cells that develops as a result of a reactivation of varicella zoster virus, the same virus that causes chickenpox. 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<sup>2</sup>. Reactivation of the virus is thought to be associated with immunosuppression as a result of a decline in cell mediated immunity. Increasing age, immunosuppressant therapy or HIV infection are all thought to increase the risk of developing shingles<sup>3</sup>.

### Who does it affect?

Shingles can develop at any time following a chickenpox infection and can occur in individuals of any age. However, the risk and severity of shingles increases with age.

Thus the burden of disease amongst adults aged 70 and above is considerably

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<sup>1</sup> Joint Committee on Vaccination and Immunisation (2010) Statement on varicella and herpes zoster vaccines 29 March 2013. [internet] accessed 30 August 2014

[http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@ab/documents/digitalasset/dh\\_133599.pdf](http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_133599.pdf)

<sup>2</sup> NHS Choices (2014). Shingles. [internet] accessed 30 August 2014  
<http://www.nhs.uk/Conditions/Shingles/Pages/Introduction.aspx>

<sup>3</sup> Department of Health (2013) Immunisation against infectious diseases: shingles Chapter, TSO Publishing, Crown Copyright. <http://immunisation.dh.gov.uk/green-book-chapters/>

greater than younger adults<sup>4</sup>. Older adults tend to experience a severe form of the disease which can result in secondary complications including persistent pain or postherpetic neuralgia (PHN) and secondary bacterial skin infections that may require hospitalisation.

## The shingles vaccination programme

### What is the purpose of the programme?

The purpose of the programme is to reduce the incidence and severity of shingles disease in adults aged 70 years and above<sup>3</sup>. Offering the shingles vaccine routinely to individuals at the age of 70 years aims to boost immunity in individuals with pre-existing VZV immunity to prevent the development of shingles in later years and significantly reduce the incidence of PHN.

A one dose schedule of Zostavax® was assessed in clinical trials using 17,775 adults aged 70 years and over. The study demonstrated that the vaccine reduced the incidence of shingles by 38% and boosted immunity for at least 5 years. For those immunised with Zostavax® but who later developed shingles, the vaccine significantly reduced the burden of illness by 55% and significantly reduced the incidence of PHN by 66.8%.

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<sup>4</sup> van Hoek AJ, Gay N, Melegaro A et al. (2009) Estimating the costeffectiveness of vaccination against herpes zoster in England and Wales. *Vaccine* 27(9): 1454-67. Cited in Joint Committee on Vaccination and Immunisation (2010) Statement on varicella and herpes zoster vaccines 29 March 2013. [internet] accessed 30 August 2014  
[http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@ab/documents/digitalasset/dh\\_133599.pdf](http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_133599.pdf)

## Who is the vaccine recommended for?

The key factor to consider when determining eligibility for the programme in 2015/16 is the patients age, in years, on the 1 September 2015. The following cohorts are **eligible** to receive the vaccine from 1 September 2015.

Cohort	Those eligible for immunisation
Routine	Patients aged 70 years on 1 September 2015
Catch up	Patients aged 78 years on 1 September 2015
*Additional cohorts	1. Patients aged 71 and 72 on 1 September 2015 And 2. Patients aged 79 on 1 September 2015

\*- Those who were eligible for immunisation in the first two years of the programme but who have not been vaccinated against shingles remain eligible until their 80<sup>th</sup> birthday.

## What is the recommended vaccine for the programme?

Zostavax® is the recommended vaccine for the programme and is the only market-authorized shingles vaccine in the UK.

Zostavax® is a live attenuated vaccine that contains a high antigen content of varicella zoster virus (Oka/Merck Strain, not less than 19400PFU)<sup>5</sup>.

Zostavax® , the vaccine for the national programme can be ordered via the **ImmForm** website. Healthcare professionals should refer to the ImmForm website on a regular basis for up to date information on vaccine availability.

## What are the contraindications for receiving Zostavax® ?

As Zostavax® is a live attenuated vaccine, it should **not** be given to a person in the following groups:

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<sup>5</sup> Sanofi Pastuer MSD Limited (2013) Zostavax SPC. [internet] accessed on 30 August 2014  
<http://www.medicines.org.uk/emc/medicine/25927>

1. **Primary or acquired immunodeficiency states** due to conditions including:

- acute and chronic leukaemias, lymphoma
- immunosuppression due to HIV/AIDS
- cellular immune deficiencies
- those remaining under follow up for a chronic lymphoproliferative disorder including haematological malignancies such as indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (NB: this list not exhaustive)
- those who have received a solid organ transplant and are currently on immunosuppressive therapy
- those who have received an allogenic stem cell transplant (cells from a donor) or an autologous stem cell transplant (own cells) in the past 24 months

2. **Immunosuppressive or immunomodulating therapy** including:-

- those on current or recent immunosuppressive chemotherapy or radiotherapy for malignant disease in the last 6 months
- those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy such as alemtuzumab, ofatumumab and rituximab) unless otherwise directed by a specialist
- those who are receiving or have received in the past 3 months immunosuppressive therapy including
  - i) short term high-dose corticosteroids (>40mg prednisolone per day for more than 1 week);
  - ii) long term lower dose corticosteroids (>20mg prednisolone per day for more than 14 days)
  - iii) non-biological oral immune modulating drugs e.g. methotrexate >25mg per week, azathioprine >3.0mg/kg/day or 6-mercaptopurine >1.5mg/kg/day

Zostavax® is **not** contraindicated for use in individuals who are receiving topical/inhaled corticosteroids or corticosteroid replacement therapy. Long term stable low dose corticosteroid therapy (defined as  $\leq 20$ mg prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate  $\leq 25$ mg per week, azathioprine  $\leq 3.0$ mg/kg/day or 6-mercaptopurine  $\leq 1.5$ mg/kg/day) are **not** considered sufficiently immunosuppressive and these patients can receive the vaccine.

Specialist advice should be sought for other treatment regimes.

3. **Confirmed anaphylactic reaction** to a previous dose of varicella – containing vaccine or any component of the vaccine, including neomycin or gelatin

#### 4. Pregnancy

- Zostavax® is not indicated in women of childbearing age. Women who are pregnant should not receive Zostavax®.

### Special considerations for vaccination of eligible individuals in clinical risk groups

To support the assessment of **patients eligible for the national programme in clinical risk groups**, the following information may be used as a guide in determining patients suitability for the vaccine.

**The decision to administer Zostavax® to such individuals should be based on obtaining complete clinical information to undertake the assessment. If the individual is under highly specialist care, and it may not be possible to obtain full information on that individual's treatment history, then vaccination should not proceed until the advice of the specialist or a local immunologist has been sought.**

#### 1. Malignancy

Eligible individuals who have undergone immunosuppressive chemotherapy or radiotherapy for malignant and non-malignant disorders (other than lymphoproliferative disorders, see section on haematological disorders) should not receive Zostavax® until 6 months after the end of treatment **and** they are demonstrated to be in remission. Primary healthcare professionals managing such patients may wish to discuss the patient's eligibility to receive the vaccine with the secondary care specialist or immunologist prior to administration.

Immunosuppressed individuals who are inadvertently vaccinated with Zostavax® should be urgently assessed to establish the degree of immunosuppression. As all individuals of this age group should be VZV antibody positive, varicella-zoster immunoglobulin is unlikely to be of benefit but prophylactic aciclovir may be considered in those for whom the attenuated vaccine virus poses a significant risk. Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with aciclovir, given the risks and severity of disseminated zoster.

As a precautionary measure, any person who develops a vesicular rash after receiving Zostavax® should ensure the rash area is kept covered when in contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted. If the person who received the vaccine is themselves immunosuppressed, they should avoid contact with susceptible people until the rash is dry and crusted, due to the higher risk of virus shedding.

In addition to the precautionary measures outlined above, a vesicle fluid sample should also be sent for analysis to confirm the diagnosis and determine whether the rash is vaccine associated or wild type. This service is available at the Virus Reference Department (VRD) at



Public Health England, Colindale (T: 0208 327 6266). Please note sampling kits are **not** supplied by the Virus Reference Department at Public Health England. Health professionals are requested to obtain vesicle swabs from their local hospital laboratories. **Forms and instructions on how to take a vesicle fluid sample can be found here** .

## 2. Haematological disorders including haematopoietic stem cell transplants

Patients with chronic lymphoproliferative malignancies e.g. indolent lymphoma, chronic lymphoid leukaemia, myeloma and other plasma cell dyscrasias (abnormalities) should not receive Zostavax®.

Patients who have received an allogenic haematopoietic transplant (using stem cells from a donor) should not receive Zostavax® until at least 24 months following transplantation and only then if they are demonstrated not to have ongoing immunosuppression or graft versus host disease(GVHD).

Those patients who have received autologous (using your own stem cells) haematopoietic stem cell transplant with curative intent e.g. for a high grade lymphoma should **not** receive Zostavax® until 24 months after transplant **and** only then if they are in remission. Patients with Hodgkin's lymphomas should **not** receive Zostavax®.

For patients with autoimmune haematological disorders receiving immunosuppressive therapy, please see section 2 under contraindications.

## 3. Solid Organ Transplants

Those who have received a solid organ transplant and are currently on immunosuppressive therapy should not receive Zostavax®. The decision to vaccinate eligible patients should depend upon the type of transplant and the immune status of the patient. Primary healthcare professionals may wish to discuss the patient's eligibility with a secondary care specialist or immunologist prior to administration.

The decision to vaccinate should depend upon the type of transplant and the immune status of the patient.

## 4. Chronic Inflammatory disorders on immunosuppressive or immunomodulating therapies e.g. Rheumatoid arthritis, Inflammatory bowel disease, psoriasis, glomerulonephritis

Many adults with chronic inflammatory diseases may be on stable long term low dose corticosteroid therapy (defined as  $\leq 20$ mg prednisolone per day for more than 14 days) either alone or in combination with other immunosuppressive drugs including biological and non-biological therapies. Therapy with stable long term low-dose corticosteroid therapy, either alone or in combination with low dose **non-biological** oral modulating

drugs are not contraindications for administration of zoster vaccine. These include methotrexate  $\leq 25$ mg per week, Azathioprine ( $\leq 3.0$ mg/kg/day), or 6-mercaptopurine ( $\leq 1.5$  mg/kg/day).

Those who are receiving or have received in the past 12 months **biological** therapies (e.g. anti-TNF therapy) should **not** receive Zostavax® unless otherwise directed by a specialist.

**Specialists with responsibility for patients in the vaccine eligible cohorts should include a statement of their opinion on the patient's suitability for Zostavax® in their correspondence with primary care. If primary healthcare professionals administering the vaccine have concerns about the nature of therapies (including biologics) or the degree of immunosuppression they should contact the relevant specialist for advice.**

#### 5. Patients anticipating immunosuppressive therapy

The risk and severity of shingles is considerably higher amongst immunosuppressed individuals and therefore eligible individuals anticipating immunosuppressive therapy should ideally be assessed for vaccine eligibility **before** starting treatment that may contra-indicate future vaccination.

Eligible individuals who have not received Zostavax® should receive a single dose of vaccine at the earliest opportunity and at least 14 days before starting immunosuppressive therapy, although leaving one month would be preferable if a delay is possible<sup>3</sup>.

#### 6. HIV infection

The safety and efficacy of Zostavax® have not been conclusively established in adults who are known to be infected with HIV with or without evidence of immunosuppression. On basis of limited Phase II trial data<sup>6</sup> and extrapolation from other live vaccines<sup>7</sup>, a CD4 count of 200 cells/ $\mu$ l may be a suitable cut off value below which vaccination should **not** be given. Immunosuppressed patients who require protection against shingles should seek advice from a secondary care specialist.

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<sup>6</sup> Benson C, Hua L, Andersen J, et al. (2012) ZOSTAVAX is generally safe and immunogenic in HIV+ adults virologically suppressed on ART: results of a phase 2, randomized, double-blind, placebo-controlled trial. Program and abstracts of the 19th Conference on Retroviruses and Opportunistic Infections; March 5-8, 2012; Seattle, Washington. Abstract 96

<sup>7</sup> Koenig HC, Garland JM, Weissman D, Mounzer K. (2013). Vaccinating HIV patients: focus on human papillomavirus and herpes zoster vaccines. AIDS Rev. Apr-Jun;15(2):77-86

## 7. Cellular immune deficiencies other than HIV infection

Patients with cellular immune deficiencies should not receive Zostavax®. However, humoral deficiencies affecting IgG or IgA antibodies are not of themselves a contraindication unless associated with T cell deficiencies. If there is any doubt (e.g. common variable immune deficiency), immunological advice should be sought prior to administration.

### Can Zostavax® be administered to patients with Rheumatoid Arthritis (RA)?

Patients with rheumatoid arthritis (RA) are at an increased risk of developing shingles infection as compared to the general population. It is therefore important that all eligible patients with RA are clinically assessed for their suitability to receive Zostavax as they have significant ability to benefit. Where possible, eligible patients with RA should be offered the vaccine prior to commencing treatment with non-biological or biological therapies, i.e. recombinant monoclonal antibody therapy.

Eligible patients who have already commenced treatment with non-biological therapies may also be considered for shingles vaccination. However, for those patients who have already commenced biological therapy, Zostavax® should **not** be administered.

As patients receiving immunosuppressive therapy for rheumatological conditions will usually be under the care of a rheumatologist, the BSR recommends that eligible patients are clinically assessed by their specialist and that the specialist then liaises with primary care to advise on individual patient suitability for the vaccine.

### Can Zostavax® be administered to patients with Inflammatory bowel disease?

Patients with inflammatory bowel disease (IBD) are at an increased risk of developing shingles as compared to the general population. Where possible, eligible patients with IBD should be offered the vaccine prior to commencing treatment with immunomodulating or biological therapies.

It is recommended that eligible patients receiving immunosuppressive therapy for IBD should be assessed by their gastroenterologist who should then liaise with primary care to advise on individual patient suitability for the vaccine.

## Can Zostavax® be administered to patients with dermatological conditions e.g. Psoriasis?

The risk of shingles infection is increased with advancing age, prolonged treatment with oral corticosteroid, and with immunosuppressive and biological agents. As these therapeutic agents may be used in the management of dermatological conditions, patients eligible for the national programme should be clinically assessed for their suitability to receive Zostavax® prior to commencing treatment, as they may benefit significantly from receiving it.

Eligible patients should be considered for vaccination prior to commencement of biological and non-biological therapies. Therapy with stable long term low-dose corticosteroid therapy, either alone or in combination with low dose non-biological oral modulating drugs are not contraindications for administration of zoster vaccine. These include methotrexate  $\leq 25$ mg per week, Azathioprine ( $\leq 3.0$ mg/kg/day), or 6-mercaptopurine ( $\leq 1.5$  mg/kg/day).

However, patients already established on biological therapy, such as etanercept and infliximab, should **not** receive Zostavax®.

It is recommended that eligible patients receiving immunosuppressive therapy for a dermatological condition should be assessed by their dermatologist who should then liaise with primary care to advise on the individual patient suitability for the vaccine.

## Can Zostavax® be administered to patients with renal conditions e.g. glomerulonephritis or reduced renal function?

Patients with impaired renal function and/or receiving immunosuppression for inflammatory renal diseases will have an increased risk of shingles as well as reduced vaccine responses and may have reduced clearance of oral immunosuppressants and their active metabolites including azathioprine, methotrexate and 6-mercaptopurine.

Patients requiring low dose oral immunosuppression for inflammatory renal disease with preserved kidney function who are in remission could be considered for Zostavax® if they are receiving long term stable low dose corticosteroid therapy (defined as  $\leq 20$ mg prednisolone per day for more than 14 days) either alone or in combination with low dose non-biological oral immune modulating drugs (e.g. methotrexate  $\leq 25$ mg per week, azathioprine  $\leq 3.0$ mg/kg/day or 6-mercaptopurine  $\leq 1.5$ mg/kg/day).

Primary care physicians may wish to discuss the suitability of Zostavax® with the secondary care physician responsible for managing the immunosuppression for those patients with impaired, particularly severely impaired, renal function who are also receiving long term stable low dose non-biological oral immune modulating drugs (e.g. methotrexate  $\leq 25$ mg per week, azathioprine  $\leq 3.0$ mg/kg/day or 6-mercaptopurine  $\leq 1.5$ mg/kg/day) alone or in

combination with low dose corticosteroid therapy (defined as  $\leq 20$ mg prednisolone per day for more than 14 days).

Zostavax® is contraindicated for some patients with inflammatory renal disease including:

- those whose inflammatory disease is not in remission
- those on current or recent immunosuppressive chemotherapy in the last 6 months
- those who are receiving or have received in the past 12 months biological therapy (e.g. anti-TNF therapy)
- those who are receiving or have received in the past 3 months immunosuppressive therapy including
  - i) short term high-dose corticosteroids ( $>40$ mg prednisolone per day for more than 1 week);
  - ii) long term lower dose corticosteroids ( $>20$ mg prednisolone per day for more than 14 days)
  - iii) non-biological oral immune modulating drugs e.g. methotrexate  $>25$ mg per week, azathioprine  $>3.0$ mg/kg/day or 6-mercaptopurine  $>1.5$ mg/kg/day

### Can Zostavax® be administered to patients with an absent or dysfunctional spleen?

Eligible patients who have an absent or dysfunctional spleen should be offered Zostavax®, **unless otherwise contraindicated** as they have a significant ability to benefit from the vaccine. Whilst there is no evidence relating specifically to the use of Zostavax® in splenectomy patients, asplenia or a dysfunctional spleen is not considered a contraindication to receiving the vaccine.

Live and inactivated vaccines are safely administered to children and adults with an absent or dysfunctional spleen routinely<sup>8</sup> in primary care to offer protection against a range of vaccine preventable diseases.

However, whilst asplenia itself is not a contraindication to receiving Zostavax®, it is important for healthcare professionals to be aware of the underlying cause that has resulted in the

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<sup>8</sup> British Committee for Standards in Haematology (2011) Review of guidelines for the prevention and treatment of infection in patients with an absent or dysfunctional spleen.  
[http://www.bcshguidelines.com/4\\_HAEMATOLOGY\\_GUIDELINES.html?dtype=All&dstatus=Current&dsdorder=&dstorder=&dmax=10&dsearch=splenectomy](http://www.bcshguidelines.com/4_HAEMATOLOGY_GUIDELINES.html?dtype=All&dstatus=Current&dsdorder=&dstorder=&dmax=10&dsearch=splenectomy)

absent or dysfunctional spleen, as this may be a contraindication to receiving the vaccine. For example, leukaemic infiltration is a potential reason for splenectomy, and so the patient may have an acute leukaemia which is one of the specific contraindications to use of Zostavax®.

Additionally, offering the shingles vaccine to eligible patients who are asplenic or who have a dysfunctional spleen provides an opportunity for the clinician to ensure the patient is up-to-date with all the recommended vaccines for asplenic patients, as documented in chapter 7 of the Green Book.

## Special precautions

### *Antiviral agents*

There is a potential for antiviral agents to lower the effectiveness of Zostavax®. Therefore, Zostavax® should not be administered to eligible patients currently receiving oral or intravenous (IV) antiviral agents (such as aciclovir) or who are within 48 hours after cessation of treatment as the therapy may reduce the response to the vaccine.

Where possible antiviral therapies should not be started within two weeks after receiving Zostavax® as this may adversely affect the effectiveness of the vaccine.

The use of topical antiviral agents such as aciclovir is not a contraindication to vaccination. Eligible patients currently receiving topical antiviral agents should be offered Zostavax® as nationally recommended.

## What adverse reactions are commonly associated with the administration of Zostavax® ?

The most commonly reported adverse reactions affecting 1 in 10 of those receiving the vaccine includes erythema (redness), pain, swelling and pruritus (itching) at the injection site. Other less commonly reported reactions affecting 1 in 100 includes haematoma, induration and warmth at the injection site.

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

## Vaccine eligibility for the national programme

### Can the vaccine be offered to individuals outside of the national programme?

Those who are **not** eligible to receive the vaccine as part of the national programme, but who wish to pay for the vaccine privately should be encouraged to discuss their request with a private provider.

GPs are not able to charge their own patients (i.e. those registered at their practice) a private fee for the vaccine and should not use centrally procured stock for the national programme to vaccinate private patients. Patients seeking the vaccine privately should be made aware that they will be liable for the full costs of the vaccine and any additional administration charges that the private provider may apply.

### How will the programme be delivered?

Zostavax® is available through GP surgeries in primary care.

GPs are encouraged to identify and offer the shingles vaccination to eligible patients. For convenience, the shingles vaccine can be administered at the same time when patients are called for the seasonal influenza vaccine and/or 23-valent pneumococcal polysaccharide vaccine (PPV). However, scheduling of the appointment should not delay the administration of any of these vaccines. The shingles vaccine can be administered outside of the influenza vaccine season where the two vaccines have not been given together.

If given at the same time as influenza vaccinations, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. Additionally, given that some individuals eligible for seasonal influenza vaccination may be immunosuppressed, it is important to check that there are no contraindications to administering the live Zostavax® vaccine to these clinical risk groups.

### What if an individual does not have a previous history of chickenpox; should they still be offered the vaccine?

Yes, a previous clinical history of chickenpox infection is not a pre-requisite for receiving Zostavax® .

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. Therefore, the vaccine should still be offered to individuals without a clinical history of chickenpox to ensure protection against zoster<sup>5</sup>.

**What if an individual who is eligible for the national programme presents with a previous history of shingles infection; should they still be offered the vaccine?**

Immunocompetent individuals who present with a recent history of shingles infection should have their vaccination delayed for one year as boosting from natural infection is likely to offer protection at least until this time.

**Should individuals outside of the national programme with a previous history of shingles infection (including recurrent shingles infections) be offered Zostavax® ?**

Individuals within this age group who present with a previous history of shingles (including recurrent shingles infections), should be reassured that having natural infection will help to boost the individual's immune response to the virus. Therefore, such individuals should wait until they become eligible for the national programme, allowing a one year interval period between vaccination and the last episode of infection.

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.

**Can Zostavax® be given to an individual who is currently diagnosed with shingles infection?**

No. Zostavax® is not licensed for the treatment of shingles or shingles related postherpetic neuralgia (PHN). Eligible individuals presenting with shingles infection should defer immunisation for a period of one year.

## Vaccine administration

**How is the vaccine administered?**

In January 2016 the shingles vaccine (Zostavax®) was licensed for administration via the intramuscular (IM) or subcutaneous (SC) routes. However, as injection-site adverse



reactions were significantly less frequent in those who received the vaccine via the IM route, **IM** administration is **preferred** for those who do not have bleeding disorders.

Where an eligible patient presents with a bleeding disorder, administration via the SC route is recommended.

The vaccine comes in a box that contains a vial and pre-filled syringe for reconstitution. Once reconstituted, the mixture should form a semi-hazy to translucent, off-white to pale yellow liquid that should be administered immediately. Each pack is a single dose with a volume of 0.65ml after reconstitution

Healthcare professionals are encouraged to read the Summary of Product Characteristics to ensure accurate reconstitution of the product.

### Does Zostavax® contain latex?

No, Zostavax® does not contain latex.

### Does Zostavax® contain any preservatives such as thiomersal?

No, Zostavax® does not contain any thiomersal.

### We have heard that Zostavax® contains ingredients that come from pork – is this true?

The shingles vaccine Zostavax® does contain hydrolysed gelatine derived from pork as one of its additives. Gelatine is commonly used in a range of pharmaceutical products, including many capsules and some vaccines. The gelatine used in Zostavax® is a highly purified product used to stabilise live viral vaccines.

### Is it permissible for those of certain faiths to receive the vaccine?

This statement from representatives of the Jewish community may help your patients to reach a decision about having the vaccine:

Rabbi Abraham Adler from the Kashrus and Medicines Information Service, said:

It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, including those administered via the nose, injections, suppositories, creams and ointments.

However, we also acknowledge that some groups within the British Muslim community may consider the porcine product to be forbidden. In this circumstance, the individual would be

unable to accept many pharmaceutical products unless there was no suitable alternative and/or the product was considered life-saving.

### Is there an alternative live vaccine that does not contain porcine products?

No, Zostavax® is the **only** vaccine recommended by the Department of Health for the prevention of shingles and shingles related PHN. At this time, there is no alternative shingles vaccine available. Public Health England's statement<sup>9</sup> on vaccines and gelatine can be found [here](#)

### What action should be taken if Zostavax® is inadvertently administered orally?

Inadvertently administering Zostavax® via the oral route is unlikely to cause significant harm as it is expected that the attenuated virus will be neutralised by the gastrointestinal tract.

Health professionals should inform the patient of the administration error, provide reassurance where necessary and encourage the patient to seek medical assistance if they become unwell. If the patient was eligible to receive Zostavax®, then an additional dose administered via the recommended subcutaneous route should be offered as soon as possible.

Inadvertently administering Zostavax® via the oral route is a serious clinical incident that should be taken seriously and reported immediately via the local governance system(s), so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

### What action should be taken in the event that Zostavax® is inadvertently administered during pregnancy?

As a precautionary measure, health professionals should treat the inadvertent administration of Zostavax® vaccine in a pregnant woman in the same way as a natural exposure to chickenpox infection and should urgently assess the woman's susceptibility to chickenpox.

Those women who give a reliable history of chickenpox infection or who have documented evidence of receiving two doses of varicella vaccine should be reassured that they are immune and that the inadvertent administration of Zostavax® will boost their existing antibodies against varicella zoster virus (chickenpox). These women should be provided with [information on the safety of varicella vaccines when given in pregnancy leaflet](#) and advised that no further action is required.

For those women who are unable to give a reliable history of chickenpox infection or documented evidence of varicella vaccination, an urgent varicella antibody test (VZV IgG)

should be performed using either the women's booking bloods or arrange a blood sample to be taken. It is important for healthcare professionals to liaise directly with the local microbiologist to arrange urgent testing and timely reporting of results. Those women who are found to be VZV IgG positive should be reassured that they are immune and that the inadvertent administration of Zostavax® will boost their existing antibodies against varicella zoster virus (chickenpox). These women should be provided with [information on the safety of varicella vaccines when given in pregnancy leaflet](#) and advised that no further action is required. For those women with a VZV IgG equivocal result, we recommend that the local laboratory re-test the sample using a more sensitive assay e.g Binding Site to confirm the result.

For those women who are found to be VZV IgG negative on testing, please contact the duty doctor at Public Health England (PHE) Colindale (T: 020 8200 4400) for further advice and consideration of the use of VZIG within 10 days of inadvertent vaccination. Ideally, VZIG should be administered within 7 days where practically possible but can be offered up to 10 days following vaccination. Samples from those pregnant women found to be VZV IgG negative on local testing will be requested to be sent to the Virus Reference Department for storage. These samples will not be routinely tested but may undergo further testing should the need arise later in pregnancy. Further guidance on the management of pregnant women exposed to a vesicular rash can be found in the [viral rash in pregnancy](#) guidance document.

All incidents of inadvertent administration of Zostavax® during pregnancy should also be reported to Public Health England using the [vaccines administered in pregnancy reporting form \(VIP\)](#). This national surveillance collects additional information on such exposures so that we can better inform health professionals and pregnant women in the future.

Inadvertently administering Zostavax® during pregnancy is a serious clinical incident that should be reported immediately via the local governance system(s), so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

### [Can Zostavax® be administered at the same time as other vaccines?](#)

Yes. Zostavax® can be administered concomitantly with other vaccines such as inactivated influenza and 23-valent pneumococcal polysaccharide vaccine (PPV)<sup>3,10</sup> and live vaccines such as Yellow Fever and MMR. Zostavax® can also be administered at the same time or before or after other live vaccines, **except** MMR. If MMR is required and this cannot be administered at the same time as Zostavax®, a four week interval period is ideally recommended.

The JCVI has recently agreed that the interval period between the administration of live vaccines (currently four weeks) is no longer applicable, except for Yellow Fever and

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<sup>9</sup> Public Health England (2013) Vaccines and Gelatin: PHE's response.

<https://www.gov.uk/government/news/vaccines-and-gelatine-phe-response> [last accessed 20 November 2014].

<sup>10</sup> Tseng HF, Smith N, Sy LS, Jacobsen SJ. Evaluation of the incidence of herpes zoster after concomitant administration of zoster vaccine and polysaccharide pneumococcal vaccine. *Vaccine* 2011;29(20):3628–32.

MMR (these vaccines should **not** be administered at the same time; a four week interval period is recommended) and MMR and Varicella (where these vaccines cannot be administered at the same time, a four week interval period is recommended). Therefore excepting these vaccines, live vaccines can be administered at any time before or after other live vaccines.

Where more than one vaccine is administered at the same time, the vaccines should be given at a separate site, preferably in a different limb. If more than one vaccine is given in the same limb, they should be given at least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual's health records.

Please refer to [vaccine eligibility for the national programme](#) for information on how the programme will be delivered.

**The vaccine Summary of Product Characteristics states that Zostavax® should not be administered at the same time as 23- valent pneumococcal polysaccharide vaccine; why does your advice differ?**

Zostavax® can be given at the same time as 23-valent pneumococcal polysaccharide vaccine (PPV) for those who are eligible for both vaccines. Although a manufacturer conducted trial showed inferior VZV antibody responses in those receiving zoster vaccine and PPV-23 concomitantly than in those receiving the vaccines four weeks apart, there is no established correlation between antibody titres to VZV and protection from herpes zoster. Furthermore a more recent observational study showed that herpes zoster vaccine was equally effective whether it was administered simultaneously with PPV or four weeks apart<sup>10</sup>.

Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book may differ from those in the Summary of Product Characteristics for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed.

**What should you do if you inadvertently administer Zostavax® to an individual who is immunosuppressed in error?**

Immunosuppressed individuals who are inadvertently vaccinated with Zostavax® should be urgently assessed by a clinician to establish the degree of immunosuppression. As individuals of this age group should be VZV antibody positive, varicella-zoster immunoglobulin is unlikely to be of benefit but prophylactic aciclovir may be considered in those whom the attenuated vaccine virus poses a significant risk.

**Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with aciclovir<sup>3</sup>.** Please refer to **what action should a person take if they develop a vesicular rash after receiving Zostavax®** section of this document for detailed guidance on testing arrangements for those who develop of vesicular rash following the administration of Zostavax® .

Healthcare professionals should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised. Please ensure that all relevant staff are familiar with the Zostavax® packaging.

### **What should you do if you inadvertently administer Zostavax® to a child in error?**

Please ensure that all relevant staff are familiar with the Zostavax® packaging.

Although Zostavax® is similar to the varicella vaccine, it has significantly higher antigen content. Early trials in susceptible children used vaccine at doses approaching the range used in Zostavax® . The high dose formulation was well tolerated and efficacious. Inadvertent vaccination with Zostavax® in varicella naïve children is unlikely to result in serious adverse reactions and should count as a valid dose of varicella vaccine.

Healthcare professionals should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

### **What should you do if you inadvertently administer varicella vaccine (Varivax or Varilrix) to an adult instead of Zostavax® ?**

Please ensure that all relevant staff are familiar with the Zostavax® packaging.

Varicella vaccines contains a significantly lower antigen content than Zostavax® and are unlikely to provide the same level of protection against herpes zoster. Therefore, the varicella vaccine should be discounted and a further dose of Zostavax® should be offered.

Varivax, Varilrix and Zostavax® are all live attenuated vaccines. Therefore, Zostavax® should be administered at the same visit following the inadvertent administration of varicella or, if this is not possible, allowing a four-week interval between doses. Healthcare professionals should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons

can be learnt and the risk of future errors minimised.

### Can Zostavax® be used to as an alternative to Varivax or Varilrix for the prevention of chickenpox infection (varicella zoster)?

No. Zostavax® is licensed for the immunisation of individuals aged 50 years and above for the prevention of shingles (Herpes Zoster) and shingles related post herpetic neuralgia. Varivax and Varilrix are licensed vaccines for the prevention of primary varicella (chickenpox) infection and should continue to be administered as recommended in the Green Book.

### What action should a person take if they develop a vesicular rash after receiving Zostavax® ?

Although transmission of the Zostavax® vaccine virus (Orka/Merck strain) has not been reported during clinical trials, any person developing a vesicular rash after receiving Zostavax® should be tested, as recommended below.

Manufacturer experience with varicella (chickenpox) vaccines that use a lower dose of the same virus strain, suggest that transmission of vaccine virus may occur rarely between vaccinees that develop a varicella-zoster virus (VZV)-like rash and susceptible close contacts<sup>5</sup>.

As a precautionary measure, any person who develops a vesicular rash after receiving Zostavax® should ensure the rash area is kept covered when in contact with a susceptible (chickenpox naïve) person until the rash is dry and crusted. If the person who received the vaccine is themselves immunosuppressed, they should avoid contact with susceptible people until the rash is dry and crusted, due to the higher risk of virus shedding. **Immunosuppressed individuals who develop a varicella rash following inadvertent vaccination should be urgently assessed and offered prompt treatment with acyclovir.**<sup>3</sup>

In addition to the precautionary measures outlined above, a vesicle fluid sample should also be sent for analysis to confirm the diagnosis and determine whether the rash is vaccine associated. All samples should be sent to the Virus Reference Department (VRD) at Public Health England, Colindale (T: 0208 327 6266). Please note sampling kits are **not** supplied by the Virus Reference Department at Public Health England. Health professionals are encouraged to obtain sampling kits as per local arrangements. **Forms and instructions on how to take a vesicular sample can be found here** .

Contact tracing is not required if an immunocompetent person develops a localised vesicular rash following vaccination.

## Where can I get further information?

Public Health England and NHS England Joint Letter (2015). *Shingles immunisation programme from 1 September 2015*

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/450328/150514\\_Shingles\\_Letter\\_2015\\_final\\_v4.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/450328/150514_Shingles_Letter_2015_final_v4.pdf)

Public Health England (2014) *The characteristics, management and surveillance of shingles (herpes zoster)*. <https://www.gov.uk/government/collections/shingles-vaccination-programme>

Department of Health (2015) Immunisation against infectious diseases: *shingles Chapter*, TSO Publishing, Crown Copyright. <http://immunisation.dh.gov.uk/green-book-chapters/>

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<http://www.nhs.uk/Conditions/Shingles/Pages/Introduction.aspx>