NHS England

Publications Gateway Reference 00366

PATIENT GROUP DIRECTION (PGD)

Administration of Zostavax® reconstituted lyophilised suspension.
Shingles (herpes zoster) vaccine, live

Adults aged 70 to 79 years

For the supply of Zostavax® reconstituted lyophilised suspension (Shingles vaccine, live) by nurses currently registered with the Nursing and Midwifery Council (NMC), to adults aged 70 to 79 years.

Reference no:	*Shingles PGD*
Version no:	*Version final*
Valid from:	*1st September 2013*
Review date:	*31st August 2014*
Expiry date:	*31st August 2015*

Public Health England is not a legal authority for the authorisation of PGDs.

Each organisation using this PGD must ensure that it is formally authorised and signed by a governance lead for the organisation so that this document meets legal requirements for a PGD. The PGD is not legal or valid without this local, formal authorisation.

THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

This Patient Group Direction has been produced by Public Health England to assist organisations such as NHS England Area Teams or others to develop and authorise a PGD that is consistent with current national guidance.

1. Clinical condition or situation to which the direction applies.

Indication	Zostavax® is indicated for vaccination of individuals aged 70 – 79 years of age for the prevention of herpes zoster ("zoster" or shingles) and herpes zoster-related post-herpetic neuralgia (PHN). Its use is in line with the recommendations given in Chapter 28a of *Immunisation Against Infectious Disease: The Green Book.* Zostavax® is authorised for use from age 50 years and is effective in this age group but vaccine use in individuals younger than 70 years and 80 years or older, is outside the scope of this PGD and the national shingles immunisation programme. In such cases, the patient's General Practitioner (GP) should refer to the manufacturer's Summary of Product Characteristics, issue a patient specific direction (PSD) or administer the vaccine themselves. **Note: It is unlikely that Zostavax® will be available outside of that supplied for the national programme. There may be some limited supply for those aged 71-78 years.**
Objective of programme	The objective of the national shingles immunisation programme is to provide a single dose of Zostavax® vaccine to adults from 70 years of age and before 80 years of age, in order to prevent herpes zoster (shingles) and herpes zoster-related post-herpetic neuralgia (PHN). The impact and cost effectiveness of vaccination is greatest in those aged 70 to 79 years of age. In this first year of the programme (2013-14), **the vaccine will only be offered to those aged 70 and 79 years** with those between these ages brought into the programme gradually in subsequent years.
Criteria for inclusion	Adults aged 70 and 79 years of age. The minimum age for a single dose of Zostavax® is 70 years of age The maximum age for a single dose of Zostavax® is up until the day before the individual's 80th birthday.
Criteria for exclusion[1]	People who: • Have had a confirmed anaphylactic reaction to a previous dose of varicella vaccine; • Have had a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or gelatine; • Have primary or acquired immunodeficiency state due to conditions such as: acute and chronic leukaemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS

[1] Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it would be outside the remit of the PGD and another form of authorisation will be required.

	cellular immune deficiencies; • Are receiving immunosuppressive therapy including high-dose corticosteroids (see below and Chapter 6 of *Immunisation Against Infectious Disease: The Green Book* for further guidance). The safety and efficacy of Zostavax® has not been established in adults who are known to be infected with HIV (see section on action if excluded below). Zostavax® is **not contraindicated** for use in individuals who are receiving topical/inhaled corticosteroids, low-dose systemic corticosteroids (<40mg per day of Prednisolone), corticosteroid replacement therapy or other low-dose immunosuppressive therapy (methotrexate <0.4 mg/Kg/week, azathioprine <3.0 mg/Kg/day, or 6mercaptopurine <1.5 mg/Kg/day). **Temporary Exclusion** Administration of Zostavax® should be postponed in individuals suffering from acute severe febrile illness until they are completely recovered. 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. Administration of Zostavax® should be delayed until **systemic** therapy with anti-viral medicines, such as acyclovir, is completed, as these medicines may reduce the response to the vaccine.
Action if excluded	If in the eligible age group, but may be excluded on medical grounds as above, seek advice from a Consultant in Health Protection and/ or the patient's clinician, as appropriate. When considering the use of the vaccine in individuals with HIV or other severe chronic disease, the individual's General Practitioner (GP) should issue a patient specific direction (PSD) or administer the vaccine themselves. The GP should always involve the individual's specialist clinician in the decision whether to vaccinate. The risk to the individual of not being vaccinated must be taken into account. **Temporary exclusion** In case of postponement due to acute illness or short-term anti-viral therapy, arrange a future date for vaccination (if the individual will still be within the age range above). Document all decisions in the individual's clinical records. In a GP practice setting, inform or refer to the GP.

Action if patient declines treatment	Advise the patient/ their carer about the protective effects of the vaccine and the risks of the disease, including potential complications. Document advice given and decision reached. In a GP practice setting, inform and/ or refer to the GP.
Reference to national / local policies or guidelines	Chapter 28a of *Immunisation Against Infectious Disease: The Green Book.* Joint letter from Department of Health, NHS England and Public Health England 12th July 2013.
Precautions	See also Special considerations especially on inadvertent vaccination of immunosuppressed individuals. Zostavax® is not recommended for the treatment of shingles or post herpetic neuralgia (PHN). The natural boosting of immunity that occurs following an episode of shingles, makes it of limited value to offer zoster vaccine immediately following recovery. Individuals who have shingles or PHN should wait until symptoms have ceased (and usually considerably longer) before being considered for shingles immunisation. **Transmission** Transmission of vaccine virus may occur rarely between those vaccinated and susceptible contacts, even in the absence of a varicella-like rash. Individuals who do develop a varicella-like rash after vaccination with Zostavax® should avoid direct contact with a susceptible (chicken pox naïve) person until the rash is dry and crusted. Please see Chapter 28a of *Immunisation Against Infectious Disease: The Green Book* for more details.

2. Description of Treatment

Name, strength & formulation of drug	After reconstitution, Zostavax® lyophilised suspension (0.65ml) contains **Shingles (herpes zoster) vaccine**, consisting of live attenuated virus derived from **varicella zoster** virus.
Presentation	Zostavax® vaccine is supplied as single packs only and contains shingles (herpes zoster) vaccine (live) as: • A white to off-white powder (compact crystalline plug) in a glass vial with a butyl rubber stopper and aluminium flip-off cap • A clear colourless fluid solvent in a pre-filled glass syringe with a rubber plunger stopper and tip cap • Two unattached needles. When reconstituted, Zostavax® is a semi-hazy to translucent, off-white to pale yellow liquid.
Storage	Store in the original packaging at +2°C to +8°C and protect from light. Do not freeze and avoid contact with disinfectants. Shelf life is 18 months. After reconstitution the vaccine should be used immediately. However, the in-use stability has been demonstrated for 30 minutes when stored at 20°C - 25°C.
Legal status	Prescription Only Medicine (POM).
Black Triangle▼	No.
Unlicensed / off label use	Yes, only with respect to concomitant use of pneumococcal vaccine, see section on Drug interactions below.
Route / method	**Reconstitution of the product before administration:** 1. Inject all the solvent in the pre-filled syringe into the vial of lyophilised vaccine and agitate gently to mix thoroughly 2. Withdraw the entire contents into a syringe for injection 3. Needles should be pushed into the extremity of the syringe and rotated a quarter of a turn (90°) to secure the connection. **It is recommended that the vaccine be administered immediately after reconstitution, to minimize loss of potency. Discard reconstituted vaccine if it is not used within 30 minutes.** Note: • Separate needles should be used for the reconstitution and

	administration of the vaccine • The product must not be mixed with other medicinal products in the same syringe • Avoid contact with disinfectants • Discard the vaccine if there is any particulate matter present or the appearance of solvent or reconstituted vaccine, differ from the description in the section on Presentation. **Instructions for administration of the vaccine:** Zostavax® vaccine is given as a single dose by subcutaneous injection, preferably in the deltoid region of the upper arm. Zostavax® should NOT be injected intramuscularly or intravascularly (this may be revised in future). The Summary of Product Characteristics for Zostavax® provides further guidance on administration and is available from the **European Medicines Agency website**: **http://www.medicines.org.uk/EMC/medicine/25927/SPC/Zostavax/**
Dose	Single dose of 0.65 ml of Zostavax® vaccine at age 70 – 79 years of age. See sections on inclusion and exclusion criteria above for this year's programme.
Frequency of administration	See section on Dose.
Duration of treatment	See section on Dose.
Supply	See section on Presentation.
Total doses	Single 0.65ml dose of Zostavax®
Disposal	Equipment used for immunisation, including used vials, ampoules, or partially discharged vaccines in a syringe, should be disposed of at the end of a session by sealing in a proper, puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01 (Department of Health, 2006).
Drug interactions	None reported. Zostavax® can be given at the same time as inactivated influenza vaccine, preferably at different body sites or at least 2.5cm apart. **However, Zostavax® should NOT be given to patients with primary or acquired immunodeficiency and must be given by subcutaneous injection.** See section above on Criteria for Exclusion.

	Zostavax® can also be given at the same time as 23-valent pneumococcal polysaccharide vaccine, preferably at different body sites or at least 2.5cm apart; on balance the evidence suggests that there is no reduction in the effectiveness of the Zostavax®. If other live attenuated vaccines, such as Yellow fever are required, these should either be given simultaneously or after a four week interval to ensure adequate protection from the second vaccine given. There is no data on concomitant use with anti-viral medications but it is likely that these will reduce the response to Zostavax® **Please see Chapter 28a of *Immunisation Against Infectious Disease: The Green Book* for more details.**
Identification & management of adverse reactions	The most common adverse reactions observed after administration of Zostavax® vaccine are injection site reactions, including redness, swelling, pain and itching. Other relatively common reactions include bruising, hardening (induration) and warmth at the injection site, headache and pain in the relevant limb. Very rarely a varicella (chickenpox) - like illness has been reported. A detailed list of adverse reactions associated with Zostavax® is available in the Summary of Product Characteristics for this vaccine, which is available from the European Medicines Agency website.
Patient advice and follow up treatment	See section on Advice to patient/carer below.
Reporting procedure of adverse reactions	As with all vaccines, healthcare professionals and patients/ carers are encouraged to report suspected adverse reactions to Zostavax® to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. Any serious adverse reaction to the vaccine should be documented in the individual's medical records and their GP should be informed.
Advice to patient/carer including written information	Supply marketing authorisation holder's patient information leaflet (PIL) provided with the vaccine. Inform the individual/ their carer of possible side effects and their management. Give advice regarding normal reaction to the injection, for example redness and pain at the injection site.

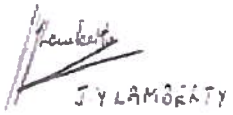
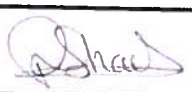
	The individual/ their carer should be advised to seek medical advice in the event of a severe adverse reaction. Also see section on Transmission above.
Special considerations and additional information	Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection, to appropriate medical supervision and to a telephone. Minor illnesses without fever or systemic upset are NOT valid reasons to postpone immunisation. In cases of acute severe febrile illness, see section above on Temporary exclusion. Inadvertant vaccination of chicken pox naïve children with Zostavax® is unlikely to cause serious adverse reactions and will be protective against chicken pox. Please note: • **The risk and severity of shingles is much higher in immunosuppressed individuals so ideally those eligible should receive Zostavax® preferably one month and at least 14 days before commencing immunosuppressive therapy;** • **All immunosuppressed individuals who are inadvertently vaccinated with Zostavax® require urgent assessment and may need to receive prophylactic acyclovir, particularly if they develop a varicella rash.** Please see Chapter 28a of *Immunisation Against Infectious Disease: The Green Book* for more details about these notes.
Records	Record: • That valid informed consent was given; • Name of patient, address, date of birth and GP with whom the infant is registered; • Name of member of staff who supplied the vaccine; • Date of supply • Dose and form of vaccine supplied; • Quantity supplied; • Batch number and expiry date; • Anatomical site of vaccination; • Advice given; • Advice given if excluded or declines vaccination; • Record how the patient's central record or GP surgery record will be updated; • Details of any Adverse Drug Reactions and actions taken; • Record supplied via Patient Group Direction (PGD). All records should be clear, legible and contemporaneous.

	This information should be recorded in the patient's GP record and any care or nursing home medical records. A computerised or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes. Clinical records must be kept for at least 8 years following completion of treatment. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

3. Characteristics of Staff

Qualifications required	Nurses currently registered with the Nursing and Midwifery Council (NMC); Other trained and appropriately qualified professionals as detailed in Chapter 5 of *Immunisation Against Infectious Disease: The Green Book.*
Additional requirements	• You must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction (PGD) before working to it; • You must have undertaken appropriate training for working under a PGD for supply of medicines; • You must have undertaken training appropriate to this PGD; • You must be competent to undertake immunisation and vaccination and to discuss issues related to them; • You must be competent in the recognition and management of anaphylaxis.
Continued training requirements	• You must maintain your own level of updating with evidence of Continued Professional Development (CPD); • You should be constantly alert to any subsequent recommendations from the Department of Health and other sources of medicines and vaccine information.

4. PGD Development

Developed & produced by:	Name	Signature	Date
Senior Pharmacist	Mrs Jacqueline Lamberty		4th August 2013
Doctor (Lead Author)	Dr Penelope Toff		23rd July 2013
Primary Care Practice nurse	Priti Shah		24th July 2013

Acknowledgements

Name	Designation
Dr Mary Ramsay	Head of Immunisation, PHE
Dr Sally Millership	Consultant in Communicable Disease, PHE
Dr Gayatri Amirthalingam	Consultant Epidemiologist, PHE

5. ORGANISATIONAL AUTHORISATIONS

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met.

Complete details below or use format agreed according to local policy.

Organisation Approvals		**DATE**
Local Clinical Governance Committee e.g. DTC/MMT SMT 30/8/13	Dr DAVID BLAU	29th August 2013
Additional signatories according to local policy e.g. independent contractor providers.	M KITCHING	29/8/2013

Organisations must add an Individual Practitioner Authorisation sheet or List of Authorised Practitioners. This varies according to local policy but this should be a signature list or an individual agreement according to local policy.

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE

Practitioner

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct

Signed.....Date.....
..

Name
(Print).....

Designation.....
..

Authorising Manager

Manager to give authorisation on behalf of xxx (insert name of organisation) for the named Health Care Professional who has signed the PGD

Signed..... Date.....

Name (Print).....

Designation.....

Note to Authorising Manager

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD