Changing Landscape of Adult Immunisation and ZOSTAVAX® on the National Immunisation Program

ZOSTAVAX®
[Zoster Vaccine Live (Oka/Merck)]

Learning Outcomes

- Understand the importance of adult immunisation for older Australians
- Understand new provisions in the National Immunisation Program (NIP) for free herpes zoster (shingles) vaccination in individuals aged 70-79 years
- Understand the role of herpes zoster vaccination (ZOSTAVAX®) in helping to prevent shingles in older adults and its complications

Outline of Talk

Vaccine preventable disease in Australian adults
- Recommendations
- Addition of shingles vaccine (ZOSTAVAX®) to the NIP schedule
- Australian Immunisation Register

About Herpes Zoster (Shingles)
- Effects of shingles
- Treatment
- Prevention (vaccination)
- Efficacy/safety of ZOSTAVAX®

Strategies to implement vaccination programs in your practice
- Recall strategies
  (Case studies)

Addition of ZOSTAVAX® to the NIP from 1st November[1]

Disease[2]	Age group[2]	Vaccine brands[2]
Influenza	65 years and over	Influenza
Pneumococcal pneumonia	65 years and over 50 years and over (Aboriginal and Torres Strait Islanders)	Pneumovax®23 (pneumococcal vaccine, polyvalent)
Herpes-zoster (shingles)	70-79 years ^	ZOSTAVAX® (Zoster Vaccine Live (Oka/Merck))

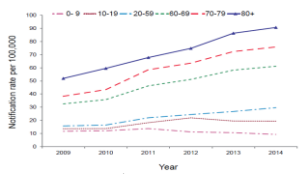
^ ZOSTAVAX® is to be provided free for 70 year olds, with a 5 year catch-up program for 71-79 year olds[1]

Refer to the National Immunisation Program for the full Immunisation schedule[1]

1. Department of Health. Shingles NIP announcement. www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/news-20152307. Accessed September 2016. 2. Australian Government Department of Health. *National Immunisation Program Schedule*. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/5403D77C07E1973ACA257D49001E3775/$File/NIP-schedule2016.pdf . Accessed September 2016

Shingles in Australia

Notification rate for shingles, Australia,* 2009 to 2014, by year and selected age groups†1



Adapted from NNDSS, 2016.[1]

Can we achieve shingles vaccine coverage comparable to influenza vaccine coverage?

*Excludes NSW
†Age of onset missing for 1 notification in 2009, 13 notifications in 2010, 18 notifications in 2011, 32 notifications in 2012, 59 notifications in 2013 and 59 notifications in 2014.

NNDSS. *Commun Dis Intell* 2016;40:E48-E145.

Australian Immunisation Register

Australia's Immunisation Registers have expanded

- From Sept 2016, the Australian Childhood Immunisation Register (ACIR) is expanded to become the Australian Immunisation Register (AIR) [1,2]
- The AIR will capture all vaccines administered throughout a person's life given through General Practice and community clinics[1]
- This will include all funded vaccines under the NIP; & private vaccines[1]
- In September 2017 new functionality will be added to allow two-way communication between the AIR and Practice Management Software[2]

1. Australian Government Department of Health. Immunise Australia program. Fact sheet. *UPDATE: Expansion of Australia's Immunisation Registers.* 23 October 2015. 2. Eastern Melbourne PHN. Immunisation Update. Available at: http://www.emphn.org.au/page/news/news/immunisation-update/ Accessed July 2016.

Benefits of the AIR for GPs & other vaccine providers[1]

- Broaden and improve immunisation data capture
- **Enable greater understanding of current coverage**
- **Give vaccination providers secure access to a range of due and overdue reports, to facilitate monitoring of vaccine uptake and help them identify the immunisation status of individuals**
- Assists in identifying areas of low coverage within Australia and enable targeted effort to boost immunisation rates in these areas

1. Australian Government Department of Health. Immunise Australia program. Fact sheet. *UPDATE: Expansion of Australia's Immunisation Registers.* 23 October 2015.

About herpes zoster ('shingles')

Shingles is unpredictable[1]

Shingles is the reactivation of the varicella-zoster virus (VZV)[2]

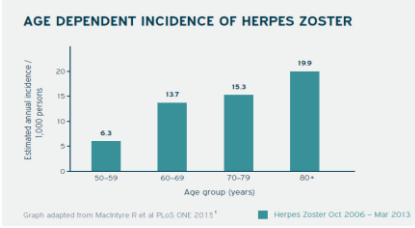
97% of adults have VZV latent within them[1]

Only 4% of adults aged 60+ believe they are at high risk of shingles[3]

Shingles is on the rise in the 60+ age group[4]

1. Stein AN *et al. Vaccine* 2009;24:520-29 2. Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016. 3. Shingles Study 150930 n=1,025. Seqirus data on file. September 2015. 12:92. 4. MacIntyre R et al Increasing Trends of Herpes Zoster in Australia. PLoS ONE 2014; 10(4):e0125025.

Incidence of shingles increases with age[1]



1. MacIntyre R *et al Increasing Trends of Herpes Zoster in Australia. PLoS ONE* 2015; 10(4):e0125025.

The risk of developing shingles is significant[1]

120,000

Annual incidence of shingles per year in Australia[1]

1 IN 3

Adults may develop shingles in their lifetime[2]

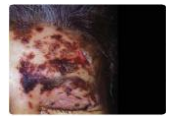
1 in 2 by 85 years old

1. MacIntyre R *et al Increasing Trends of Herpes Zoster in Australia. PLoS ONE* 2014; 10(4):e0125025. 2. Harpaz R et al. MMRW Jun 6;57(RR-5):1-30

Shingles complications

Shingles pain can be excruciating: 'stabbing and burning'

Ophthalmic zoster
- Occurs in up to 25%[1]
- Complications may include facial scarring and loss of vision[1,2]



Stroke risk
- Shingles may also increase the risk of stroke in the next 6 months[3]
- 63% higher risk in the 4 weeks after shingles vs. baseline period[3]

1. Harpaz R *et al. MMWR* 2008 (June 6); 57 (RR-5): 1-30 2. Oxman MN et al. Arvin AM et al, editors, 200 0p246/75 3. Langan SM *et al. Clin Infect Dis* 2014; 58: 1497-1503

Postherpetic neuralgia (PHN) is the most frequent debilitating complication of shingles[1]

- PHN can last for months even years[1]: min 3 months defines PHN
- Pain and nerve damage can begin before the shingles rash is visible[2]
- PHN may be severe[1,2] especially if severe pain early on
- PHN patients report experiencing pain in the area of their shingles rash for an average of 3.5 years[3]

20%

Up to 20% of adults may develop PHN[4]

1. Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016. 2. Oxman MN et al. Arvin AM et al, editors, 2000 p246/75 3. Serpell M *et al. Health Qual Life Outcomes* 2014; 12: 92. 4. Harpaz R *et al. MMWR* 2008 (June 6); 57 (RR-5): 1-30

Treatment

Treatment options for shingles[1]

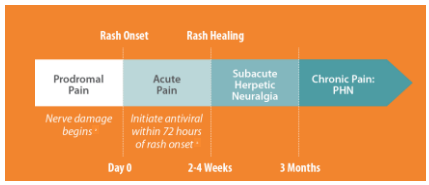
- Antiviral treatment should be commenced in immunocompetent patients who present within 72 hours of the onset of the rash

and in ***all*** immunocompromised patients regardless of rash duration
  - *Antivirals help to reduce the severity and duration of shingles*
- Adequate analgesia to manage pain include:
  - paracetamol, as well as corticosteroids, opioids and/or tricyclic antidepressants for severe pain
- Supportive care:
  - Cool compresses
  - Bathe lesions with saline to remove crusts and exudate
  - Cover the lesions with a light non-adherent padded dressing
  - **Regular monitoring by GP to check that pain adequately controlled**

1. Herpes zoster: antiviral therapy [Published November 2014]. In: eTG complete [Internet]. Melbourne: Therapeutic Guidelines Limited; 2016 Mar.

The risk of developing PHN remains substantial[1]

Virus replication causes inflammation and injury to the nerve before rash appears[2]



Cochrane Review: insufficient evidence to recommend antivirals to prevent PHN[1]

1. Chen N *et al. Cochrane Database of Systematic Reviews* 2014, Issue 2. 2. Oxman MN *et al. In: Arvin AM et al* (Eds). Varicella-Zoster Virus: Virology and Clinical Management 2000: 246-275 3. eTG complete (online) Therapeutic Guidelines 2013

Prevention by vaccination

ZOSTAVAX®
[Zoster Vaccine Live (Oka/Merck)]

ZOSTAVAX®[1]

- ZOSTAVAX® is a live-attenuated varicella-zoster virus vaccine[1]
- **ZOSTAVAX® is indicated for the prevention of:**[1]
  - **shingles in individuals 50 years of age and older**
  - **postherpetic neuralgia (PHN) and for reduction of acute and chronic zoster-associated pain in individuals 60 years of age and older**
- ZOSTAVAX ® will be provided free from 1st Nov 2016 on the National Immunisation Program for 70-79 year olds[2]

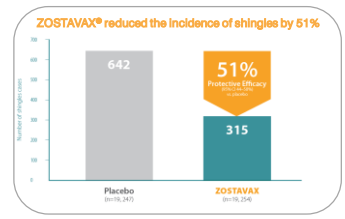
1. ZOSTAVAX® Approved Product Information. 2. Department of Health. Shingles NIP announcement. www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/news-20151207. Accessed September 2016

Shingles Prevention Study (SPS)[1]

- The pivotal efficacy trial for ZOSTAVAX®
  - Randomised, double-blind, placebo controlled trial
  - Patients received either the vaccine or placebo, and were then followed up for a median of 3.1 years
- Conducted in 38,546 adults aged 60 years and over
- The **primary endpoint was the burden of illness** due to shingles;
  - a measure affected by the incidence, severity and duration of the associated pain and discomfort
- **Secondary end point: incidence of post-herpetic neuralgia**

1. Oxman MN et al. NEJM 2005; 352:2274-84

ZOSTAVAX® significantly reduced the incidence of shingles by 51% vs placebo in adults aged 60+[1,2]

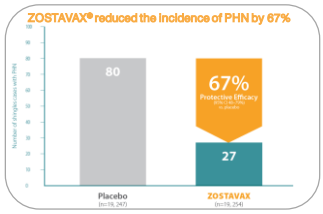


In vaccinated patients who developed shingles, ZOSTAVAX® significantly reduced shingles associated pain compared to placebo

A placebo controlled, double-blind clinical trial, 38,546 subjects aged 60 years or older were randomised to receive a single dose of either ZOSTAVAX® or placebo and were monitored for the development of shingles for a median of 3.1 years. Graph adapted from Oxman et al NEJM 2005

1. ZOSTAVAX® Approved Product Information. 2 Oxman MN et al. NEJM 2005; 352:2274-84

ZOSTAVAX® significantly reduced the incidence of PHN by 67% vs. placebo in adults aged 60+[1,2]



Patients vaccinated with ZOSTAVAX® who did develop shingles had a significantly lower incidence of PHN compared to placebo

A placebo controlled, double-blind clinical trial, 38,546 subjects aged 60 years or older were randomised to receive a single dose of either ZOSTAVAX® or placebo and were monitored for the development of shingles for a median of 3.1 years.
PHN – post herpetic neuralgia defined as pain and discomfort associated with shingles rated as 3 or more, on a scale ranging from 0 (no pain) to 10 (pain as bad as you can imagine), persisting or appearing more than 90 days after the onset of rash. Graph adapted from Oxman et al NEJM 2005

1. ZOSTAVAX® Approved Product Information. 2. Oxman MN et al. NEJM 2005; 352:2274-84

Duration of protection

- The Shingles Prevention Study (SPS) demonstrated vaccine efficacy through 4 years post vaccination[1,2]
- A follow on Short-Term Persistence Substudy (STPS) demonstrated persistence of vaccine efficacy for at least 5 years[3,4]
- A Long-Term Persistence Substudy (LTPS) further showed vaccine efficacy remained significant against herpes zoster up to 8 years post vaccination
  - However the interpretation of this result is limited due to the methodological limitations in that study[3,5]
- The need for a booster dose of ZOSATAVAX is not yet evaluated[2,3]

1. Oxman et al. In Arvin AM et al, editors. 2000: 246-275 2. ZOSTAVAX® Approved Product Information 3. Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016. 4. Schmader et al. Clin Inf Dis 2012;54(7):922-928 5. Morrison et al. Clin Inf Dis 2015;60(6):900-909

ZOSTAVAX® is contraindicated in patients with:[1]

- History of hypersensitivity to any component of the vaccine, including gelatin
- History of anaphylactic/anaphylactoid reaction to neomycin
- Primary and acquired immunodeficiency states e.g. leukaemia, lymphoma, conditions affecting bone marrow or lymphatic system, immunosuppression due to AIDS, cellular immune deficiencies
- Immunosuppressive therapy (including high-dose corticosteroids)
- Active untreated tuberculosis
- Pregnancy

ZOSTAVAX® Approved Product Information.

Persons significantly immunocompromised should not receive ZOSTAVAX®[1,2]

- Unless a contraindication or precaution exists, ZOSTAVAX® may be given to patients receiving[1]
  - topical/inhaled corticosteroids,
  - low-dose systemic corticosteroids or
  - corticosteroids as replacement therapy, e.g. for adrenal insufficiency
- Seek specialist advice for immunocompromised patients[1,2]

and refer to NCIRS factsheet

1. ZOSTAVAX® Approved Product Information. 2. Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health; 2016.

ZOSTAVAX® is generally well tolerated

- In clinical trials, ZOSTAVAX® has been evaluated for safety in more than 32,000 adults 50 years of age and older [1]
- The most common adverse events (≥10%) reported in clinical trials were[1]
  - Erythema, pain/tenderness, swelling and pruritus
- Over 33 million doses of ZOSTAVAX® have been distributed worldwide since 2006[2]
- Results from "real world" post marketing safety studies support the safety profile seen in clinical trials[3,4]

To report an adverse event contact
CSL Medical Information: 1800 642 865
Email: MedicalInformation.Aust@csl.com.au

1. ZOSTAVAX® Product Information. 2. Seqirus Data on file 3. Baxter et al Vaccine 2012; 30(47):6636-6641 4. Tseng et al Journal of Internal Medicine 2012;271(5):510-20

ZOSTAVAX® use with other vaccines[1]

- ZOSTAVAX® can be administered concurrently with inactivated influenza vaccine as separate injections at different sites
- ZOSTAVAX® and PNEUMOVAX 23 should not be given concomitantly
  - concomitant use resulted in reduced immunogenicity of ZOSTAVAX®
  - Consider administration of the two vaccines separated by at least 4 weeks

1. ZOSTAVAX® Approved Product Information

ZOSTAVAX® dosage and administration[1]

- Individuals should receive a single dose (0.65mL) of the vaccine **subcutaneously**
- Reconstitute immediately after removal from fridge
- Administer the vaccine immediately after reconstitution (discard if not used within 30 minutes)

Refer to product information for further information

ZOSTAVAX® Approved Product Information

Strategies to implement vaccination programs in your practice

The importance of recall programs[1]

- **GPs and practice nurses are important influencers**
  - **Patient attitudes about shingles vaccination are strongly influenced by GP recommendations[1]**
- Immunisation rates can significantly improve when a recall system is in place[2]
  - A recall system involves proactive follow-up of patients
  - A recall system can be tailored to your practice with a choice of different immunisation models
- **The unpredictable nature of shingles increases the importance of recalling patients to be vaccinated promptly**

1. Litt JCB, *et al. Int J Infect Diseases* 2014; 21:436-7. 2. Szilagyi PG *et al. JAMA* 2000; 284(14): 1820-27.

Consider immunisation models to improve uptake rates

November 1st provides opportune time to consider different immunisation models and schedule recall programs to improve uptake rates within your practice

Regular vaccine clinics
- Practice allocate set days and times to run dedicated immunisation-only sessions, usually with a designated clinician

Opportunistic vaccination
- Practice or clinicians would identify and offer vaccination to eligible patients as they present to the practice for other reasons

Standard appointments
- Patients are encouraged to book a standard appointment with their GP to be vaccinated

Out of surgery clinics
- For providers who offer immunisation sessions outside of the practice

Resources

The Australian Immunisation Handbook 10th Edition (2016 update)

www.communityimmunity.com.au
- Recall resources
- Vaccine management resources

community immunity
immunisation resource

www.shingles.com.au
- Download patient education information about shingles

Vaccine-preventable disease in adults

How well are we doing at immunising older adults in Australia?

Vaccine preventable disease (VPD) in older Australians

- Older adults have a higher incidence of many infectious diseases, and tend to respond less well to treatment[1]
- Immunisation against VPD is important for older age groups – but vaccination rates are suboptimal[2]
- The immune system 'weakens' with age, but this does not preclude a robust immune response to vaccines[3,4]
- The population health benefits of vaccinating older adults, with a higher burden of disease but reduced ability to respond to vaccines, is greater than the population health benefit of vaccinating younger adults[4]

1. ANZSGM, *Australasian J Ageing* 2016;35-73. 2.Australia Institute of Health and Welfare 2011. 2009 Adult Vaccination Survey: Summary results. Cat. no. PHE 13. Canberra: AIHW. 3. MacIntyre CR *et al. PLoS ONE* 2014; 9: e94578. doi:10.1371/journal.pone.0094578 4. MacIntyre R. *The Conversation* June 18, 2014. http://theconversation.com/vaccination-is-not-for-kids-a-guide-for-over-65s-27989

Current vaccines provided free to older Australians under the National Immunisation Program (NIP)[1]

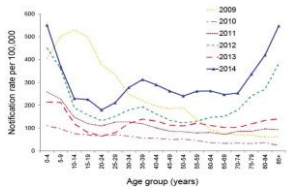
Disease	Age group	Vaccine brands
Influenza	65 years and over	Influenza
Pneumococcal Pneumonia	65 years and over 50 years and over (Aboriginal and Torres Strait Islanders)	Pneumovax® 23 (pneumococcal vaccine, polyvalent)

Refer to the National Immunisation Program for the full Immunisation schedule[1]

1. Australian Government Department of Health. *National Immunisation Program Schedule*. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/5403D77C07E1973ACA257D49001E3775/$File/NIP-schedule2016.pdf , Accessed September 2016.

Influenza in Australia

Notification rate for laboratory confirmed influenza, Australia, 2009 to 2014, by age group[1]



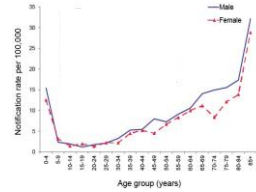
Adapted from NNDSS, 2016.[1]

75% seasonal influenza vaccine coverage in adults aged ≥65 years in 2009[2]

1. NNDSS *Commun Dis Intell* 2016;40:E48-E145. 2. Australia Institute of Health and Welfare 2011. 2009 Adult Vaccination Survey: Summary results. Cat. no. PHE 13. Canberra: AIHW.

Invasive pneumococcal disease in Australia

Notification rate for laboratory confirmed invasive pneumococcal disease, 2014, by age group[1]



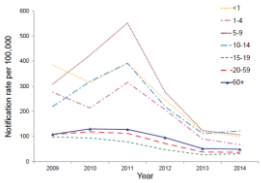
Adapted from NNDSS, 2016.[1]

54% pneumococcal pneumonia vaccine coverage in adults aged ≥65 years in 2009[2]

1. NNDSS *Commun Dis Intell* 2016;40:E48-E145. 2. Australia Institute of Health and Welfare 2011. 2009 Adult Vaccination Survey: Summary results. Cat. no. PHE 13. Canberra: AIHW.

Pertussis in Australia

Notification rates for pertussis, Australia, 2009 to 2014, by year and selected age groups*[1]



Adapted from NNDSS, 2016.[1]

*Excludes 16 cases reported without age

45% pertussis vaccine coverage in adolescents and adults 2009[2]

1. NNDSS *Commun Dis Intell* 2016;40:E48-E145. 2. Australian Government Department Health and Ageing. 2008. 2008 Adult Vaccination Survey: Summary Results

Case studies

Case 1

- Dawn is a healthy 70-year-old woman who moved from Vietnam to Australia 20 years ago
- She is not sure if she has had chickenpox before
- She has heard about the free shingles vaccine and would like to be vaccinated

Question

Would you assume Dawn has been exposed to VZV?

Question

Would you offer the shingles vaccine to Dawn?

Vaccination of varicella-zoster virus-naïve individuals

- VZV exposure may be significantly lower in some tropical countries[1]
- However, neither history of previous varicella infection nor evidence of prior immunity to VZV is required prior to the routine administration of the shingles vaccine[2]
- Studies of the administration of a high-dose VZV-containing vaccine to VZV seronegative adults, compared with previously infected adults, suggest that the vaccine was well tolerated and immunogenic in seronegative persons[3]

1. Cunningham AL *et al. MJA* 2008; 188: 171-76. 2. Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016. 3. Macaladad N *et al. Vaccine* 2007; 25: 2139-44.

Could varicella vaccination be more appropriate?

- If there *is* laboratory evidence of a lack of immunity to VZV, and the patient does not have a history of age-appropriate varicella vaccination, they should be vaccinated with 2 doses of varicella vaccine, rather than shingles vaccine

Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016.

Case 2

- Bob is 77 years old
- He says he had shingles 8 years ago, and he was in excruciating pain (he is not a regular patient, so you do not have a record of this)
- He is in good health
- He knows someone who recently had shingles twice, and he wants to ensure that doesn't happen to him

Question

Would you recommend shingles vaccination for Bob?

It's possible to develop shingles more than once

- While recurrence is uncommon among immunocompetent persons, having an episode of shingles does **not** ensure protection against future episodes[1]
  - Estimated 5% recurrence rate[1,2]
  - Recurrence more likely in:[1]
    - Immunocompromised patients
    - Patients who experienced longer duration of pain with initial episode
- ZOSTAVAX® can be given to someone who has had shingles[2,3]
  - The length of time following an episode of shingles after which it would be reasonable to vaccinate has not been established.
  - The Australian Immunisation Handbook suggests that the vaccine could be given at least one year after the shingles episode.[2]

1. Yawn et al Mayo Clin Proc 2011;86:88-93. 2. Australian Technical Advisory Group on Immunisation (ATAGI). *The Australian immunisation handbook* 10th ed (2016 update). Canberra: Australian Government Department of Health, 2016. 3. ZOSTAVAX® Approved Product Information

Question

Bob is planning to attend the clinic for flu & pneumococcal vaccination next month, and he would like to receive the shingles vaccine on the same day

Would you recommend this?

Co-administration with ZOSTAVAX®

- Can be administered concurrently with inactivated influenza vaccine as separate injections at different sites
- ZOSTAVAX® and PNEUMOVAX® 23 should not be given concomitantly because concomitant use resulted in reduced immunogenicity of ZOSTAVAX®. Consider administration of the two vaccines separated by at least 4 weeks.
- Refer to Product Information for further information

ZOSTAVAX® Approved Product Information

Case 3

- Judy is 72 years old
- Currently taking 15 mg/day prednisolone for polymyalgia rheumatica
- She has heard about the free availability of the vaccine and would like to be vaccinated

Question

Would you recommend vaccination for Judy?

Contraindications

- Primary and acquired immunodeficiency states due to conditions such as: acute and chronic leukaemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS; cellular immune deficiencies.
- Immunosuppressive therapy (including high-dose corticosteroids);

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Persons significantly immunocompromised should not receive the zoster vaccine

Unless a contraindication or precaution exists, ZOSTAVAX® may be given to:

- Patients receiving
  - topical/inhaled corticosteroids,
  - low-dose systemic corticosteroids or
  - corticosteroids as replacement therapy, e.g. for adrenal insufficiency

ZOSTAVAX® Approved Product Information

Questions?

Before prescribing, please review the Product Information available at www.seqirus.com.au/PI

MINIMUM PRODUCT INFORMATION

ZOSTAVAX® Zoster Virus Vaccine Live (Oka/Merck), Refrigerator stable

Indications: Prevention of herpes zoster (shingles) in individuals 50 years of age and older. Prevention of postherpetic neuralgia (PHN) and reduction of acute and chronic zoster-associated pain in individuals 60 years of age and older. ***Contraindications:** History of hypersensitivity to any component of the vaccine, including gelatin. History of anaphylactic/anaphylactoid reaction to neomycin. Primary and acquired immunodeficiency states due to conditions such as: acute and chronic leukaemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS; cellular immune deficiencies. Immunosuppressive therapy including high-dose corticosteroids, but not topical/inhaled corticosteroids. ZOSTAVAX is a live, attenuated varicella-zoster vaccine and administration may result in disseminated disease in immunosuppressed or immunodeficient patients. Active untreated tuberculosis. Pregnancy (see PRECAUTIONS). **Precautions:** Adequate treatment provisions, including adrenalin injection (1:1000), should be available for immediate use should an anaphylactic/anaphylactoid reaction occur. Consider deferral of vaccination in the presence of fever >38.5°C. Safety and efficacy not established in adults known to be infected with HIV. ***Use in Pregnancy (Category B2)*** Do not administer to pregnant females, pregnancy should be avoided for 3 months after vaccination. ***Use in Lactation*** It is not known whether VZV is secreted in human milk. ***Use in the elderly*** The mean age of subjects enrolled in the largest (N=38,546) clinical study of ZOSTAVAX was 69 years (range 59-99 years). ZOSTAVAX was demonstrated to be generally safe and effective in this population. ***Interactions with other medicines:** ZOSTAVAX can be administered concurrently with inactivated influenza vaccine. ZOSTAVAX and PNEUMOVAX 23 should not be given concomitantly because concomitant use resulted in reduced immunogenicity of ZOSTAVAX. Consider administration of the two vaccines separated by at least 4 weeks. **Adverse Effects:** headache, erythema, pain/tenderness, swelling, pruritus, fatigue, haematoma, warmth, induration, pain in extremity. **Post-marketing experience:** varicella, zoster, nausea, arthralgia, myalgia, injection-site rash, injection-site urticaria, pyrexia, transient injection-site lymphadenopathy, hypersensitivity reactions including anaphylactic reactions, rash, necrotizing retinitis. **Dosage and Administration:** A single dose (0.65mL) administered subcutaneously. Administer vaccine immediately after reconstitution to minimise loss of potency. ZOSTAVAX is not a treatment for zoster or PHN. Based on Approved Product Information dated 28 April 2016. Date of preparation May 2016.

*Please see change(s) in Product Information

PBS Information: This Product is not listed on the PBS or the National Immunisation Program (NIP)

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