Zoster vaccine

FREQUENTLY ASKED QUESTIONS: INFORMATION FOR IMMUNISATION PROVIDERS

This fact sheet provides responses to common questions about zoster disease and zoster vaccine. More detailed information can be found in the NCIRS fact sheet Zoster vaccine for Australian adults.

The safety of administering zoster vaccine should always be considered on a case-by-case basis. Where safety is uncertain, delay vaccination and seek expert opinion from the patient’s treating specialist and/or an immunisation expert.

What is zoster?
Zoster (or shingles) is a reactivation of the varicella-zoster virus in someone who has previously had varicella (or chickenpox) disease. Shingles commonly presents as a painful, unilateral, self-limiting vesicular rash in a dermatomal (band of skin) distribution. Often, generalised symptoms such as headache and malaise accompany the rash.

What are the complications?
Although usually a self-limiting infection lasting 10 to 15 days, in rare cases shingles can lead to serious illness including pneumonia, hearing problems, blindness, encephalitis or death. The most common complication of shingles is post-herpetic neuralgia (PHN) which is defined as persistent chronic neuropathic pain occurring at the site of the rash and persisting for more than 90 days after rash onset. This pain can have severe effects on quality of life and can be difficult to treat.

Who is at risk?
Overall, 20–30% of people will develop shingles in their lifetime, most after the age of 50 years. Almost all adults are at risk of developing shingles since more than 95% of the Australian population aged over 30 years has been infected with varicella-zoster virus (as chickenpox). The risk of developing shingles increases with age and is increased in people who are immunocompromised. The risk of developing PHN also increases with age and is highest in adults over 70 years of age.

What is the zoster vaccine and how does it work?
Only one brand of zoster vaccine (Zostavax, Merck Sharp & Dohme) is available. The vaccine has been registered for use in Australia since 2006 as a single dose for adults aged 50 years and over. Zostavax contains live attenuated varicella-zoster virus, with 14 times the amount of virus that is in the chickenpox vaccine. The efficacy of Zostavax in preventing shingles declines with age. However, protection against development of PHN is the same in people aged 70–79 years as it is for people in their 60s. This means that if a vaccinated person gets shingles, it may be less severe. Studies suggest that protection from the vaccine wanes to near zero by about 5–10 years after vaccination. A booster dose is not currently recommended. If this changes in the future, vaccine recipients and immunisation providers will be advised.

Who should be vaccinated?
Zostavax is funded for all adults aged 70 years through the National Immunisation Program (NIP). A single catch-up dose will also be funded through the NIP for adults 71–79 years of age until October 2021.

Adults in other age groups (i.e. those aged 50–69 years or 80 years and over) can also be vaccinated if they wish to purchase the vaccine (estimated vaccine cost $200); this is discussed in more detail in The Australian Immunisation Handbook.
How does Zostavax get recorded on the new Australian Immunisation Register (AIR)?

The new Australian Immunisation Register (AIR), also known as the ‘whole-of-life register’ was launched in October 2016 and should be used to record all Zostavax doses given. Detailed information on how to use the AIR is available at www.immunise.health.gov.au. The AIR will capture all NIP vaccines given to Australians throughout their life through GPs, vaccination clinics and pharmacies. The AIR is an extension of the Australian Childhood Immunisation Register (ACIR) which recorded vaccines given up to 7 years of age until 31 December 2015, and up to 20 years of age from 1 January to 30 September 2016.

Why is the vaccine funded for 70–79-year olds? What about other age groups?

The likelihood of people in this age group developing PHN after shingles is about 25%, which is significantly higher than in younger people. Although vaccine efficacy against shingles is lower in this age group, the efficacy against PHN is 66%. This, taken together with evidence of waning immunity by 5–10 years after vaccination, means that, at a population health level, immunisation is most cost-effective in this age group. The table below is a summary of vaccine efficacy against shingles and PHN by age group.

<table>
<thead>
<tr>
<th>Registered age groups</th>
<th>Vaccine efficacy</th>
<th>Likelihood of developing PHN</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>50–59 years</td>
<td>~70%</td>
<td>* Low</td>
<td>Individual benefit likely</td>
</tr>
<tr>
<td>60–69 years</td>
<td>64%</td>
<td>66% Moderate</td>
<td>Individual benefit likely</td>
</tr>
<tr>
<td>70–79 years</td>
<td>41%</td>
<td>67% High</td>
<td>NIP funded</td>
</tr>
<tr>
<td>≥80 years</td>
<td>18%</td>
<td>** Very High</td>
<td>Individual benefit still possible</td>
</tr>
</tbody>
</table>

* PHN efficacy not known: insufficient PHN cases to assess.
** PHN efficacy not known: insufficient participants/zoster cases in clinical trials to study efficacy against PHN.

Are there others who should especially be considered for vaccination?

Persons with chronic conditions, such as splenectomy, diabetes, rheumatoid arthritis, inflammatory bowel disease, dermatologic conditions (e.g. psoriasis), cardiorespiratory disease or renal disease (e.g. glomerulonephritis or reduced renal function), should be vaccinated if they are not immunocompromised since they may have a higher risk of morbidity and mortality due to shingles.

Vaccination is recommended for persons 50 years of age and over who are household contacts of an immunocompromised person in order to reduce the risk of transmission. If a vaccinated person develops a rash, they should cover the rash and avoid contact with the immunocompromised person for the duration of the rash.

Are there any side effects associated with receiving the vaccine?

Reactions at the injection site, such as pain, swelling and redness, occur in approximately 50% of vaccine recipients. These are typically mild reactions and resolve in a few days. Fever >38.3°C has been reported to occur in fewer than 0.1% of vaccine recipients.

Who should not receive zoster vaccine?

Zoster vaccine should not be given to people who are immunocompromised, pregnant women, or those who have previously had anaphylaxis to the vaccine (either Zostavax or varicella vaccine) or its components (including gelatin or neomycin).

Immunocompromising conditions that would contraindicate zoster vaccination include:

- Primary or acquired immunodeficiency
  - Haematologic neoplasms: leukaemias, lymphomas, myelodysplastic syndromes
- Post-transplant: solid organ (on immunosuppressive therapy), haematopoietic stem cell transplant (within 24 months)
- Immunocompromised due to primary or acquired (HIV/AIDS) immunodeficiency
- Other significantly immunocompromising conditions

- Immunosuppressive therapy (current or recent)
  - Chemotherapy or radiotherapy
  - High-dose corticosteroids (≥20 mg of prednisone per day, or equivalent) for ≥14 days
  - All biologics and most disease-modifying anti-rheumatic drugs (DMARDs)

**Can patients receiving disease-modifying anti-rheumatic drugs (DMARDs) be vaccinated?**

Some elderly patients are regularly taking corticosteroids and/or DMARDs. These include patients with rheumatoid arthritis, inflammatory bowel disease, dermatologic conditions, renal disease and other autoimmune or rare inflammatory conditions. Ensure that a detailed medication history is obtained prior to vaccination. As shown in the table below, zoster vaccination is usually contraindicated. However, patients taking low doses of specific DMARDs can be safely vaccinated.

<table>
<thead>
<tr>
<th>Mechanism of action</th>
<th>Examples*†</th>
<th>Safe dose‡</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-TNF</td>
<td>Etanercept</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infliximab</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IL-1 inhibition</td>
<td>Anakinra</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>Costimulation blockade</td>
<td>Abatacept</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>B-cell depletion/inhibition</td>
<td>Rituximab</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>Immunomodulators (antimetabolites)</td>
<td>Azathioprine</td>
<td>≤3.0 mg/kg/day</td>
<td>If on higher dose, vaccinate 1 month before treatment initiation OR 3 months after treatment cessation</td>
</tr>
<tr>
<td></td>
<td>Methotrexate</td>
<td>≤1.5 mg/kg/day</td>
<td></td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Prednisone</td>
<td>&lt;20 mg/day</td>
<td>If ≥20 mg/day for &lt;14 days, vaccinate 1 month before treatment initiation OR any time after treatment cessation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>If ≥20 mg/day for ≥14 days, vaccinate 1 month before treatment initiation OR 1 month after treatment cessation</td>
</tr>
<tr>
<td>Tacrolimus</td>
<td>NONE</td>
<td></td>
<td>Vaccinate 1 month before treatment initiation OR 3 months after treatment cessation</td>
</tr>
<tr>
<td>Cyclosporine</td>
<td>NONE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>Cyclophosphamide</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mycophenolate</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* **NOTE:** This is not a complete list of all licensed biologics, or medications within each class, but serves as a guide only.
† Denosumab (Prolia, Amgen Australia Pty Ltd) has been removed from this table as there is currently not enough evidence to suggest it is a contraindication to receiving Zoster vaccine.
‡ Refer to *The Australian Immunisation Handbook* 10th edition, Chapters 3.3.3 and 4.24.
Can patients receiving low-dose corticosteroids (<20 mg prednisone/day), in combination with non-biologic immune modulating therapy, be vaccinated?

Potentially, but only if each drug is not a contraindication to vaccination (i.e. low doses of azathioprine, 6-mercaptopurine or methotrexate as above). It is generally safe for individuals receiving sulfasalazine alone to receive live, attenuated zoster vaccine where there are no other contraindications. If more information on the extent of immunocompromise in an individual patient is required, seek the advice of their treating specialist and/or an immunisation expert.

Can I vaccinate my HIV-positive patient?

Persons with asymptomatic HIV infection who are on antiretroviral therapy and who have a very low or undetectable viral load and CD4+ count ≥350 per µL can be vaccinated. Where there is a strong indication to vaccinate, some experts suggest a CD4+ count of >200 per µL is safe; seek expert opinion from the treating physician and/or an immunisation specialist. Serologic confirmation of previous VZV infection must be obtained prior to vaccination.

How long do I have to wait after vaccination before starting immune modulating therapy?

Ideally, vaccination should occur at least 1 month before biologic or non-biologic immune modulating therapy is initiated. However, in extenuating circumstances on a case-by-case basis, 14 days could be considered safe.

How long should I wait after chemotherapy or radiotherapy before vaccinating a patient?

At least 6 months after the end of treatment and after patients are demonstrated to be in remission.

### Other commonly asked questions

Can I give zoster vaccine on the same day as other vaccines?

Yes, all inactivated or live vaccines (including any of the available pneumococcal vaccines) may be co-administered with zoster vaccine. If zoster vaccine is not given on the same day as other live viral vaccines (e.g. MMR, yellow fever) separate administration by 4 weeks.

Can I vaccinate someone who has had shingles?

Yes, vaccination appears safe but the optimal time for administration following an episode of shingles is uncertain. It is suggested to wait at least 1 year, and potentially up to 3 years, following an episode of shingles, since the episode itself boosts immunity. In one study it was found that both cell-mediated immunity and antibody levels after an episode of shingles in an unvaccinated patient were comparable to immunity conferred by vaccination for up to 3 years.

Does vaccination prevent shingles recurrences?

Shingles recurrence is rare and is seen in approximately 5% of cases, so prevention has not been specifically studied yet. However, vaccination 1–3 years after a shingles episode appears safe (as per above).

What if my patient has already had a dose of zoster vaccine, can I give a booster dose?

Currently, zoster vaccine is recommended as a single dose only. However, in small studies, revaccination 10 years after a previous dose appears to be safe and immunogenic.

What should I do if my vaccinated patient still gets shingles?

Manage the shingles episode as is usually recommended with laboratory confirmation (noting vaccine history) and administration of antivirals and analgesics, as appropriate.
Do I need to check VZV serology prior to vaccination?
No, not unless there are special circumstances (e.g. HIV, pre-transplant). Of note, small studies have shown that Zostavax is well tolerated and immunogenic in VZV-seronegative adults. It is acceptable to give zoster vaccine in this context, although a 2-dose course of varicella vaccine is the recommended alternative in a VZV-seronegative adult eligible for zoster vaccine.

Can I vaccinate a patient who is currently taking antivirals?
Systemic (but not topical) antiviral agents may decrease vaccine effectiveness. When possible, antivirals (e.g. acyclovir) should be stopped at least 48 hours before vaccination and withheld for at least 14 days.

What if zoster vaccine has been inadvertently given to an immunocompromised patient?
Seek immediate specialist advice to determine if the patient is severely immunocompromised. The patient will likely need close monitoring for adverse effects related to vaccine virus-associated disease, and may require prophylactic antiviral therapy.

Where vesicular lesions do arise, it is important to sample fluid by deroofing a lesion and swabbing the base with a viral swab. The sample should be sent to a reference laboratory for varicella-zoster virus PCR testing to differentiate the vaccine (Oka) strain from wild-type virus.

Additional resources for primary medical care/vaccination providers

- The Australian Immunisation Handbook, 10th edition – the most up-to-date clinical recommendations are contained in the online version of the Handbook
- Immunise Australia website
  www.immunise.health.gov.au
- For more detailed information and complete reference list see the NCIRS factsheet
  Zoster vaccine for Australian adults: information for immunisation providers