



Australian Government
Department of Health

Acting Chief Medical Officer

SAFETY ALERT: ZOSTAVAX VACCINE
NOT TO BE USED IN PEOPLE WITH COMPROMISED IMMUNE FUNCTION

Essential information:

Deaths have occurred since 2017 due to disseminated vaccine-related varicella-zoster virus infection following Zostavax administration. It is important that health professionals are aware of the potential for this very rare adverse event when considering the appropriateness of Zostavax for their patients.

Zostavax is a live, attenuated varicella-zoster virus vaccine that **must not** be given to people with current or recent severe immunocompromising conditions from either a primary or acquired medical condition or medical treatment. This includes:

- people who are immunocompromised
- people who have medical conditions that place them at risk of immunocompromise
- people receiving low doses of immunosuppressive medication.

Dear Colleague,

I am writing to provide an important update regarding the Zostavax vaccine, which is registered for use in people aged ≥ 50 years, and available under the National Immunisation Program for those aged 70-79.

Three deaths have occurred since 2017 due to disseminated vaccine-related varicella-zoster virus infection following Zostavax administration. It is important that health professionals are aware of the potential for this very rare adverse event when considering the appropriateness of Zostavax for their patients, including in patients on low dose immunosuppressive medication¹.

When considering the use of Zostavax

Zostavax must not be given to individuals who have current or recent immunocompromising conditions, from either a primary, or acquired medical condition, or medical treatment. Providers should:

- Assess patients for potentially immunocompromising conditions. If uncertain about a person's level of immunocompromise and whether vaccination is safe, do not vaccinate and seek further specialist advice. Use the **checklist** provided in the Australian Immunisation Handbook².
- Warn patients about potential adverse events, including the possibility of disseminated varicella infection.

¹ See Zostavax vaccine. TGA, 6 July 2020. Safety advisory - not to be used in people with compromised immune function: <https://www.tga.gov.au/alert/zostavax-vaccine-0>

² See Australian Immunisation Handbook – Recommendations for use of zoster vaccine in people on immunosuppressive therapy: <https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-recommendations-for-use-of-zoster-vaccine-in-people-on>

Post-administration of Zostavax

Providers and patients must be aware that disseminated varicella-zoster virus infection may present up to 2-4 weeks post-vaccination in immunocompromised patients. Patients should be advised to seek medical attention if they become unwell after receiving Zostavax, and to ensure that they mention their vaccination history.

Disseminated infection typically presents as a vesicular (chickenpox-like) rash involving multiple non-contiguous dermatomes, potentially with central nervous and pulmonary system involvement¹.

Antiviral treatment should be initiated promptly if disseminated zoster is suspected. Current treatment guidelines for disseminated varicella-zoster infection recommend antiviral therapy with famciclovir, valaciclovir or aciclovir within 72 hours of the rash appearing on the basis of clinical signs and symptoms^{2,3}. Immunocompromised patients should be admitted to hospital for intravenous aciclovir^{2,3}. Diagnosis should be based on clinical assessment with diagnostic testing as supportive so as not to delay treatment (flagged as potential vaccine-associated varicella).

Guidance on administration of Zostavax

The Australian Immunisation Handbook contains specific guidance about Zostavax administration in patients who are immunocompromised or have medical conditions that place them at risk of immunocompromise. This guidance includes a checklist on contraindications for specific immunosuppressive medications, including prednisolone, hydroxychloroquine, methotrexate and biologic agents.

The Department of Health has undertaken a range of actions to further support the safe administration of Zostavax in Australia, including:

- Updates to the Australian Immunisation Handbook to capture further safety information supporting appropriate use of the vaccine.
- working with the sponsor of Zostavax (Merck Sharp and Dohme) to include additional warning information in the vaccine Product Information.

Immunisation against herpes zoster is a key objective for the health and wellbeing of older patients in Australia. Please ensure you remain aware of the advice contained in this letter when considering the appropriateness of the Zostavax vaccine for your patients.

The Department will continue to provide updates on this issue through the Therapeutic Goods Administration website (tga.gov.au) and the Australian Immunisation Handbook (immunisationhandbook.health.gov.au).

Yours sincerely



Professor Paul Kelly
Acting Chief Medical Officer

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¹ See Varicella zoster laboratory case definition: <https://www1.health.gov.au/internet/main/publishing.nsf/Content/cda-phlnco-varicella>

² MC Wehrhahn & DE Dwyer. *Herpes zoster: epidemiology, clinical features, treatment and prevention*. Australian Prescriber, VOLUME 35: NUMBER 5: OCTOBER 2012: <https://www.nps.org.au/australian-prescriber/articles/herpes-zoster-epidemiology-clinical-features-treatment-and-prevention>

³ Shingles. Therapeutic Guidelines Ltd (eTG August 2020 edition): <https://tgldcdp.tg.org.au/viewTopic?topicfile=shingles>