

Publicly Funded Shingles (Herpes Zoster) Immunization Program: Information for Health Care Providers

This questions and answers sheet for health care professionals provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment.

Effective September 15, 2016, Ontario will introduce shingles vaccine for individuals 65 to 70 years of age, as part of Ontario's publicly funded immunization program.

Q1. What is herpes zoster?

A1. The varicella zoster virus (VZV) causes two distinct clinical syndromes: varicella (chickenpox), and zoster (shingles). Herpes zoster (HZ) infection arises from the reactivation of latent varicella zoster virus from a previous chickenpox infection.

Q2. Who is at risk for herpes zoster?

A2. Herpes zoster can develop at any time following a varicella (chickenpox) infection and can occur in individuals of any age. However, herpes zoster occurs most frequently among older adults and immunocompromised persons. Age is the most important risk factor for development of herpes zoster and two-thirds of the cases occur in individuals over 50 years of age. In addition, the severity of illness associated with herpes zoster and its complications also increases with age. Post-herpetic neuralgia is the most frequent complication of HZ, and is characterized by prolonged

and often debilitating neurogenic pain that persists for more than 90 days from the onset of rash.

Q3. What is the incidence/prevalence of herpes zoster in Canada?

A3. In recent studies, the lifetime risk of HZ has been estimated to be as high as 30 per cent in the general population. In Canada, there are an estimated 130,000 new cases of HZ, and 17,000 cases of post-herpetic neuralgia which result in 2,000 hospitalizations.

Q4. Who is eligible for the publicly funded shingles immunization program?

A4. Effective September 15, 2016, individuals ages 65 to 70 years (i.e., from the 65th birthday to the day prior to the 71st birthday) will be eligible for a dose of publicly funded herpes zoster vaccine.

PLEASE NOTE: Until December 31, 2016, individuals born in 1945 (i.e., those who have turned or will be turning 71 years of age in 2016), will be eligible for publicly funded herpes zoster vaccine through a one-time catch-up program. This one-time catch up program will end on December 31, 2016, after which individuals ages 65 to 70 years will be eligible for publicly funded herpes zoster vaccine.

Q5. How will the eligible cohort access publicly funded herpes zoster vaccine?

A5. Individuals aged 65 to 70 will be able to receive herpes zoster vaccine through their primary care provider. Primary care providers are encouraged to identify and offer the herpes zoster vaccine to their eligible patients.

Q6. What about my patients who are younger than 65 or older than 70, or those who are immunocompromised – are they eligible to receive the publicly funded vaccine?

A6. Only individuals between 65 to 70 years of age are eligible to receive a dose of publicly funded shingles vaccine. For non-eligible individuals, the vaccine can be purchased privately. Some of your patients may have private health care insurance that may cover the cost of the vaccine.

Q7. Which vaccine is used to protect against herpes zoster?

A7. Zostavax® II, manufactured by Merck Canada, is a live, attenuated virus vaccine containing a lyophilized preparation of the Oka/Merck strain of varicella-zoster virus. Zostavax® II is currently the only vaccine

licensed for use in Canada for the prevention of herpes zoster.

Zostavax® II is indicated for the prevention of shingles. It cannot be used to treat existing shingles or the pain associated with existing shingles.

Q8. What is the safety and efficacy profile of herpes zoster vaccine?

A8. Zostavax® II has been shown to be safe and effective for the prevention of herpes zoster and its complications. Based on a clinical study, the incidence of herpes zoster and post-herpetic neuralgia (the most frequent complication of acute herpes zoster), as well as the duration and severity of herpes zoster were significantly reduced in herpes zoster vaccine recipients. Overall vaccine efficacy was 51.3 per cent for herpes zoster incidence and 66.5 per cent for post-herpetic neuralgia.

Q9. What is the recommended dosing schedule?

A9. A single dose of herpes zoster vaccine should be administered subcutaneously. The vaccine can be given to those with or without a prior history of herpes zoster. The vaccine should be given at least one year following the last episode of HZ.

Please note: Individuals with a history of herpes zoster ophthalmicus (HZO) should be informed that cases of recurrent HZO following vaccine have occurred, although causality has not been established, and that the risk of recurrent HZO relative to the potential benefit of preventing future recurrences is unknown.

Q10. Are booster doses of herpes zoster vaccine recommended?

A10. The duration of protection from herpes zoster vaccination is unknown beyond seven years and it is not known whether booster doses of vaccine are beneficial. The National Advisory Committee on Immunization (NACI) believes that there is insufficient evidence at this time to recommend booster doses of herpes zoster vaccine. This remains an area of ongoing research.

Q11. What if an individual does not have a previous history of chickenpox - should they still be offered the vaccine?

A11. Yes, herpes zoster vaccine should be administered to individuals eligible for the vaccine regardless of whether or not the person has a history of varicella infection. Nearly all Canadians eligible for HZ immunization will have had prior varicella exposure, even if a diagnosis of varicella cannot be recalled. Therefore, the vaccine should still be offered to individuals to protect against herpes zoster.

Q12. Can the herpes zoster vaccine be given simultaneously with the other vaccines?

A12. As referenced in the Canadian Immunization Guide (CIG), in general, HZ vaccine may be administered concurrently with other live vaccines given by the parenteral, oral, or intranasal routes. For concurrent parenteral injections, different injection sites and separate needles and syringes should be used.

If two live parenteral vaccines are not administered concurrently, there should be

a period of at least 4 weeks before the second live parenteral vaccine is given.

Although the product monograph for Zostavax® II indicates that Zostavax® II and Pneumovax® 23 should not be given concomitantly, it should be noted that the CIG indicates that “Concomitant administration of pneumococcal 23-valent polysaccharide vaccine (Pneu-P-23) and HZ vaccine has not resulted in decreased efficacy and so the two vaccines can be given concomitantly.”

In general, influenza and pneumococcal vaccines may be administered concomitantly with the herpes zoster vaccine at a different injection site.

Q13. Are there any side effects?

A13. In studies, the most common side effects of receiving the shingles vaccine are mild and include injection site pain, swelling or redness. Other side effects that have been reported include: hard lump, itching, warmth, and bruising at the injection site. Headache and pain in an arm or leg were also reported.

Please see the product monograph for a complete list of reported side effects.

Q14. Who should not receive the herpes zoster vaccine?

A14. Zostavax® II is a live attenuated vaccine and should not be given to:

- Individuals with primary and acquired immunodeficiency states due to conditions such as: acute and chronic leukemias; lymphoma; other conditions affecting the bone marrow or lymphatic system; immunosuppression due to HIV/AIDS

- Individuals on immunosuppressive therapy (including high-dose corticosteroids)
- Individuals with a history of anaphylaxis after previous administration of the vaccine
- Individuals with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container, including gelatin or neomycin
- Individuals with active herpes zoster
- Individuals with active untreated tuberculosis
- Individuals that are pregnant

Administration of HZ vaccine should be postponed in persons suffering from severe acute illness, however, immunization should not be delayed because of minor acute illness, with or without fever.

Further information on who should not receive the herpes zoster vaccine can be found in the Canadian Immunization Guide.

Q15. How do I order herpes zoster vaccine?

A15. Health care providers are able to order herpes zoster vaccine through their vaccine supply source (i.e., local public health unit or the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS)). Information about your local public health unit can be found at: <http://www.phdapps.health.gov.on.ca/PHULocator>.

Q16. How should herpes zoster vaccine be stored?

A16. In order to ensure optimal protection, herpes zoster vaccine must be maintained at a temperature between +2°C to +8°C from the time of manufacture until the

vaccine is administered to individuals. This temperature must be monitored and maintained at all times. For additional information on provincial vaccine storage and handling requirements please refer to the Vaccine Storage and Handling Guidelines available at: http://www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/guidance.aspx#id

Q17. How should I document administration of the vaccine to the eligible cohort?

A17. As with all vaccines administered in Ontario, health care providers are expected to document administration of the vaccine in both the patient's medical record and personal immunization record (i.e., the "Yellow Card").

Q18. What is an adverse event following immunization (AEFI)? Which adverse events should I observe for?

A18. An adverse event following immunization (also known as an AEFI) is an unwanted or unexpected change in health that happens after someone receives a vaccine. An adverse event may or may not be caused by the vaccine. Prior to immunization, individuals should be advised of the benefits and risks of the herpes zoster vaccine as well as the importance of immediately reporting an AEFI.

In addition to reportable events (see **Health Protection and Promotion Act, R.S.O. 1990**) health care providers are asked to report any of the following events to their local public health unit:

- In rare instances, transmission has been documented following varicella

vaccine administration. Suspected transmission of herpes zoster vaccine-strain virus to a close household or occupational contact has not been documented and therefore should be reported as a reportable event

- Recurrent herpes zoster following immunization of individuals with a history of herpes zoster prior to immunization, noting the area of recurrence
- Recurrent herpes zoster ophthalmicus (HZO) following HZ vaccination of a person who has had a previous episode of HZO

Q19. What should I do if a patient reports an AEFI?

A19. Under section 38 of the Health Protection and Promotion Act, R.S.O. 1990, Ontario physicians, nurses, pharmacists and other health care providers (as listed under the section) are required to inform the person who consents to immunization of the importance of immediately reporting to a physician or a registered nurse in the extended class (nurse practitioner) of any reaction that may be a reportable event.

Health care providers should call their local public health unit to report the AEFI and then complete the Report of Adverse Event Following Immunization (AEFI) reporting form to document any reported AEFIs. The AEFI reporting form is available on Public Health Ontario's website:

<https://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Vaccine-Safety.aspx>

Public health units investigate adverse events following immunization (AEFI) and provide support to health care providers, individuals and their families. Public Health Ontario analyzes AEFIs that are reported in

Ontario to monitor the safety of administered vaccines and contribute to national and international vaccine safety surveillance systems.

Q20. Where can I get more information?

A20. For more information on Ontario's publicly funded immunization program including herpes zoster vaccine, please visit: <https://www.ontario.ca/page/vaccines>. You may also contact your local public health unit.

The Zostavax® II product monograph can be found at:

<http://www.merck.ca/English/Products/Pages/Vaccines.aspx>

Canadian Immunization Guide:

<http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php#>