



Influenza (Flu) Vaccine Safety

Influenza vaccines have been used in Canada to prevent the illness and its complications since 1945.

While influenza vaccines may have changed over the years, their safety standards have not, and they undergo rigorous testing all the time.

We know what side effects to expect from influenza vaccines.

Researchers have studied the safety of influenza vaccines for more than 50 years and have identified common and uncommon side effects.

Known side effects of influenza vaccines.

Common side effects that are mild and resolve within a few days are:

- redness and soreness/swelling at injection site
- headache
- fever
- fatigue
- muscle aches
- nausea

Less common but serious side effects are:

- severe allergic reactions to components of the vaccine
- Guillain-Barré syndrome (GBS)
- oculorespiratory syndrome (ORS)*



Canada continuously monitors influenza vaccine side effects using an 8-point surveillance system. The 8-point surveillance system composes of:

1. Health Canada review of vaccine safety data to minimize risk to Canadians and to provide information so they can make healthy, informed decisions.
2. Good manufacturing practices including random onsite checks by government inspectors.
3. Lot assessment for vaccine potency, safety, and purity before release.
4. Independent expert review of vaccine safety and efficacy data.
5. Canada's Vigilance Program receives reports on side effects and the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is a surveillance system that continuously monitors the safety of marketed vaccines.
6. Detection of any vaccine safety issue triggers an immediate recall of a vaccine.
7. Serious side effects are examined for causation.
8. Detections of side effects are shared with other countries.

Should you be concerned about influenza vaccine side effects?

Vaccination is a public health intervention, and no intervention is completely risk free. Vaccines are designed to prevent diseases, but they can also cause side effects. While your safety is a priority, both science and history have shown that vaccination works to protect us from disease.



Influenza (Flu) Vaccine Safety

Talk with your health care provider.

To minimize the chances of experiencing and/or managing a side effect from an influenza vaccine, your health care provider will screen you for contraindications or cautions to the vaccine, the administration of the vaccine, and monitoring for adverse reactions, as well as provide education about vaccine side effects and how to manage them.

Notes

Influenza vaccines contain very small amounts of specific ingredients such as thimerosal, aluminum, and formaldehyde. Thimerosal is a preservative used in multi-dose vials. It is not used in single-dose, pre-filled syringes. In general, influenza vaccines do not contain aluminum but may be in vaccines as an adjuvant to enhance the immune system's response. Formaldehyde is used to inactivate viruses and bacteria and is removed from vaccines during the manufacturing process.

Research suggests that both influenza vaccination and influenza illness are associated with small risks of GBS in adults, but the risk of GBS associated with influenza illness is notably higher than with vaccination.

*ORS is a condition associated with respiratory symptoms e.g., cough, chest tightness, difficulty breathing, sore throat that occurs within 24hrs following vaccination. There are few cases of ORS reported to CAEFISS each year.

References

Kwong JC, Vasa PP, Campitelli MA, Hawken S, Wilson K, Rosella LC, et al. Risk of Guillain-Barré syndrome after seasonal influenza vaccination and influenza health-care encounters: a self-controlled study. *Lancet Infect Dis.* 2013;13(9):769-76.

Macdonald N, Pickering L. Canada's eight-step vaccine safety program: Vaccine literacy. *Paediatr Child Health.* 2009 Nov;14(9):605-11. doi: 10.1093/pch/14.9.605.

National Advisory Committee on Immunization. An Advisory Committee Statement (ACS): Statement on seasonal influenza vaccine for 2023-2024. <https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2023-2024.html#11>

Public Health Agency of Canada. Canadian Immunization Guide. Vaccine safety and pharmacovigilance. <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-2-vaccine-safety/page-2-vaccine-safety.html>



gettyimages®

Credit: Prostock Studio



**Influenza
Consortium**