



Important Notice

On November 3, 2022, Health Canada authorized the use of the Moderna Spikevax BA.4/5 bivalent mRNA COVID-19 vaccine in adults 18 years of age and older.

Information regarding the use of this vaccine is available in the [Summary of National Advisory Committee on Immunization \(NACI\) updates of November 3, 2022: Recommendations on the use of Moderna Spikevax BA.4/5 bivalent mRNA \(50 mcg\) COVID-19 booster vaccine in adults](#).





Public Health
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Canada

SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF OCTOBER 7, 2022

Updated guidance on COVID-19 vaccine
booster doses in Canada

PROTECTING AND EMPOWERING CANADIANS
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PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.**

— Public Health Agency of Canada

Également disponible en français sous le titre :

Résumé de la déclaration du Comité consultatif national de l'immunisation (CCNI) du 7 octobre
2022 : Directives mises à jour sur les doses de rappel du vaccin contre la COVID-19 au Canada

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OVERVIEW

- On October 7, 2022, Health Canada authorized the Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) mRNA COVID-19 vaccine for use as a booster dose in people 12 years of age and older. This is the second bivalent Omicron-containing mRNA COVID-19 vaccine authorized for use in Canada.
- On October 7, 2022, the Public Health Agency of Canada (PHAC) released updated guidance from the National Advisory Committee on Immunization (NACI) on the use of COVID-19 vaccine booster doses in Canada. This guidance is based on current evidence, ethical principles and NACI expert opinion, and updates NACI's [Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines](#) (September 1, 2022) and [Interim guidance on planning considerations for a fall 2022 COVID-19 vaccine booster program in Canada](#) (June 29, 2022).
- NACI recommendations on the use of booster doses are based on evidence of the need (e.g., increased risk of severe illness from COVID-19 and/or waning protection) for and benefit (e.g., safety and effectiveness) of booster doses in the Canadian context.
- With regard to **who is recommended to receive a 2022 fall booster dose**, NACI continues to recommend that:
 - All individuals 65 years of age and older and individuals 12 years of age and older who are at increased risk of severe illness from COVID-19 **should be offered** a fall COVID-19 vaccine booster dose, regardless of the number of booster doses previously received. (**Strong NACI Recommendation**)
 - All other individuals 12 to 64 years of age **may be offered** a fall COVID-19 vaccine booster dose, regardless of the number of booster doses previously received. (**Discretionary NACI Recommendation**)
- With regard to the **vaccine product offered for a 2022 fall booster dose**, NACI now recommends that:
 - **A bivalent Omicron-containing mRNA COVID-19 vaccine is the preferred vaccine product for booster doses. (Strong NACI Recommendation)**
 - Individuals 12 years of age and older who are not able or willing to receive a bivalent Omicron-containing mRNA COVID-19 vaccine may be offered an original mRNA COVID-19 vaccine.
- Health Canada has authorized two bivalent Omicron-containing mRNA COVID-19 vaccines: the Moderna Spikevax BA.1 vaccine (18 years and over) and the Pfizer-BioNTech Comirnaty BA.4/5 vaccine (12 years and over).

- Booster doses of original mRNA COVID-19 vaccines continue to provide good protection against severe outcomes from COVID-19, including from Omicron infection. People who have already received an original mRNA COVID-19 vaccine as a fall booster will have good protection against serious illness and hospitalization and do not need to be revaccinated with a bivalent Omicron-containing vaccine.
- NACI continues to recommend that fall COVID-19 booster doses may be offered at an interval of 6 months after a previous COVID-19 vaccine dose or 6 months after a previous SARS-CoV-2 infection. A shorter interval of at least 3 months may be considered, particularly in the context of heightened epidemiological risk, evolving epidemiology and operational considerations for the efficient deployment of fall immunization programs. However, based on what is known at this time, it is not expected that a booster dose be routinely provided every 3 months.
- NACI continues to monitor the evolving COVID-19 situation and will update guidance as needed.

For the full statement, including supporting evidence and rationale, please see [NACI Statement: Updated guidance on the COVID-19 vaccine booster doses in Canada.](#)

For more information on the Moderna Spikevax BA.1 Bivalent (50 mcg) mRNA COVID-19 vaccine, please see [NACI Statement: Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines.](#)

For more information on interim fall booster planning considerations, including the list of individuals considered to be at an increased risk of severe illness from COVID-19, please see [NACI Statement: Interim guidance on planning considerations for a fall 2022 COVID-19 vaccine booster program in Canada.](#)

For information on booster doses in children 5 to 11 years of age, please see [NACI Statement: Recommendations on the use of a first booster dose of Pfizer-BioNTech Comirnaty COVID-19 vaccine in children 5 to 11 years of age.](#)

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the [COVID-19 vaccine chapter](#) in the [Canadian Immunization Guide \(CIG\)](#), as well as additional statements on the [NACI web page](#).

WHAT YOU NEED TO KNOW

- Consistent with other respiratory viruses, COVID-19 activity may increase in the fall and winter. Updated NACI guidance on the use of booster doses is specific to the 2022 fall booster programs, which aim to provide protection throughout the fall and winter seasons.
- When developing these recommendations, NACI reviewed the evolving epidemiology of COVID-19 in Canada; the safety of and protection provided by original and bivalent Omicron-containing mRNA COVID-19 vaccines, including preclinical evidence on the newly authorized Pfizer-BioNTech Comirnaty BA.4/5 Bivalent mRNA COVID-19 vaccine; as well as ethical, equity and acceptability considerations related to the use of Omicron-containing mRNA COVID-19 vaccines.
- Omicron is the most distinct variant of concern to date, with a number of key mutations distinguishing it from the original SARS-CoV-2 virus. The BA.4 and BA.5 Omicron subvariants are currently the dominant strains of the COVID-19 virus circulating in Canada.
- Original mRNA COVID-19 vaccines continue to provide good protection against severe outcomes from Omicron infection, including serious illness, hospitalization and death. However, evidence has shown that protection against symptomatic illness from the Omicron variant, including the BA.1, BA.4 and BA.5 Omicron subvariants, may be lower.
- Vaccine manufacturers have reformulated the original mRNA COVID-19 vaccines to include mRNA that encodes for Omicron.
- Health Canada has authorized two bivalent Omicron-containing mRNA COVID-19 vaccines for use as booster doses:
 - The Moderna Spikevax BA.1 Bivalent (50 mcg) COVID-19 vaccine is authorized for use in adults 18 years of age and older. It contains mRNA that encodes for the Omicron BA.1 subvariant in addition to mRNA that encodes for the original SARS-CoV-2 virus.
 - The Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) COVID-19 vaccine is authorized for use in individuals 12 years of age and older. It contains mRNA that encodes for the Omicron BA.4/5 subvariants in addition to mRNA that encodes for the original SARS-CoV-2 virus.
- Evidence to date shows that both of the bivalent Omicron-containing mRNA vaccines induce a stronger and more robust immune response and are expected to provide improved protection against the Omicron variant and subvariants compared to original mRNA vaccines.

- While there are currently no safety data available for the Pfizer-BioNTech Comirnaty BA.4/5 Bivalent (30 mcg) mRNA COVID-19 vaccine, post-market safety data from the use of the original Pfizer-BioNTech Comirnaty mRNA vaccine suggest that when used as a booster dose, the BA.4/5 bivalent vaccine will be well tolerated with a similar safety profile to the original Pfizer-BioNTech Comirnaty vaccine. NACI will vigilantly monitor post-market safety and surveillance data and update recommendations as needed.
- NACI will continue to monitor the evolving evidence on the bivalent Omicron-containing mRNA COVID-19 vaccines, as well as the circulation of variants in Canada, and will update guidance if there appears to be an advantage of one bivalent vaccine over another.

For the full statement, including supporting evidence and rationale, please see [NACI Statement: Updated guidance on COVID-19 vaccine booster doses in Canada](#).

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the [COVID-19 vaccine chapter](#) in the [Canadian Immunization Guide](#) (CIG), as well as additional statements on the [NACI web page](#).

QUOTES

“This new BA.4/5 bivalent booster is a welcome addition to the booster options this fall. NACI is recommending that either of the bivalent COVID-19 vaccines available in Canada are the preferred booster products for adults and adolescents, because they contain Omicron variants that are more diverse than any other SARS-CoV-2 virus. At this time, there is no evidence to suggest any meaningful difference in protection between the BA.1 and BA.4/5 bivalent booster doses and both are good options containing Omicron variants.

These bivalent vaccines signal a shift in our approach to managing COVID-19, where we see new boosters designed in a very timely way to address the need for a broad immune response against the SARS-CoV-2 virus.

Although NACI is strongly recommending a bivalent COVID-19 vaccine for the booster program, there is a large body of evidence regarding the original formulation and they are still expected to provide protection against severe disease. It is not necessary to receive another booster dose during this fall program if a booster was already received recently.”

- Dr. Shelley Deeks, NACI Chair

“This fall and winter, we could see increased COVID-19 activity with people having more contacts as they spend more time together indoors. Staying up to date with COVID-19 vaccinations, including receiving a fall booster dose as recommended helps build back protection that wanes over time to provide the best possible protection against becoming seriously ill. It is also an important way we can all help reduce the impact on our hospitals and healthcare workforce by reducing hospitalizations.

With Health Canada’s recent authorization of the Pfizer-BioNTech Comirnaty bivalent vaccine, Canada now has two COVID-19 vaccines that target the original strain of the SARS-CoV-2 virus, as well as the highly infectious Omicron variant. These bivalent vaccines are expected to provide stronger protection against Omicron variants, which are currently circulating in Canada and worldwide. I would like to reassure those of you who recently received a booster dose of an original mRNA COVID-19 vaccine that evidence continues to show that those vaccines provide good protection against severe illness and hospitalization from COVID-19. If you have recently received a booster dose of an original mRNA vaccine you do not need to be re-immunized with a bivalent mRNA vaccine at this time.

The Public Health Agency of Canada will continue to support provinces and territories as they plan and rollout their fall COVID-19 booster dose campaigns.”

- Dr. Theresa Tam, Chief Public Health Officer