



SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF FEBRUARY 17, 2022

Recommendations on the use of
Novavax Nuvaxovid COVID-19 vaccine



OVERVIEW

- On February 17, 2022, Health Canada authorized the Novavax Nuvaxovid COVID-19 vaccine for use as a primary series in people 18 years of age and over. This is the first recombinant protein subunit COVID-19 vaccine authorized for use in Canada.
- On February 17, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) on the use of the Novavax Nuvaxovid COVID-19 vaccine. These recommendations are based on current scientific evidence and NACI's expert opinion.
- Clinical trials show the Novavax Nuvaxovid COVID-19 vaccine is efficacious and has a good safety profile. This vaccine is a new option for people who have been unable or unwilling to receive an mRNA COVID-19 vaccine. NACI will continue to monitor the evidence on this vaccine as it is used in the real world.
- **For a primary series:**
 - **NACI continues to preferentially recommend that a complete primary series of an mRNA COVID-19 vaccine (Pfizer-BioNTech Comirnaty, Moderna Spikevax) *should be offered* to individuals in the authorized age group without contraindications to the vaccine.**
 - **NACI recommends that the recombinant protein subunit COVID-19 vaccine Novavax Nuvaxovid *may be offered* to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.**
 - **NACI recommends that a complete primary series of a viral vector COVID-19 vaccine (AstraZeneca Vaxzevria, Janssen) *may be offered* to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.**
- Additional guidance on options and considerations of preferred vaccine types for certain populations, as well as guidance on the use of the Novavax Nuvaxovid COVID-19 vaccine as a booster dose are outlined in the full statement.

For the full statement, please see [NACI Statement: Recommendations on the use of the Novavax Nuvaxovid COVID-19 vaccine](#).

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 website](#).

WHAT YOU NEED TO KNOW

- Health Canada authorized the Novavax Nuvaxovid COVID-19 vaccine for use as a primary series in people 18 years of age and over on February 17, 2022. The Novavax Nuvaxovid vaccine is the first recombinant protein subunit COVID-19 vaccine authorized for use in Canada.
- When developing these recommendations, NACI reviewed clinical trial data on the safety, efficacy, and immune response of the Novavax Nuvaxovid vaccine, as well as ethical considerations on the use of this vaccine in the current context of the pandemic.
- Clinical trial data available to date show that the Novavax Nuvaxovid vaccine is highly efficacious in preventing confirmed symptomatic COVID-19 disease in the short term. However, the duration of protection is not yet known and there is currently no data on the efficacy or effectiveness of the vaccine against the Delta or Omicron variants, as clinical trials were conducted before the emergence of those variants. NACI will review emerging data on the effectiveness of the vaccine as it becomes available.
- Side effects, for example, fatigue, headache and muscle pain, were typically mild and resolved within one or two days. They occurred more frequently after the second dose and were more common in adults 18 to 64 years of age compared to older adults.
- A few cases of myocarditis and/or pericarditis have been reported following the administration of the vaccine, but there is not yet enough information to determine if cases of myocarditis and/or pericarditis are related to the vaccine. NACI, PHAC and Health Canada will continue to monitor the emerging evidence on the safety of the vaccine.
- NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. A large amount of evidence on the safety and effectiveness of mRNA COVID-19 vaccines has accumulated throughout the pandemic as hundreds of millions of people have received mRNA COVID-19 vaccines around the world.
- The Novavax Nuvaxovid vaccine is a new COVID-19 vaccine option for people who have been unable, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.
- A primary series of the Novavax Nuvaxovid COVID-19 vaccine is currently considered to be two doses.
- People may receive two doses of the Novavax Nuvaxovid vaccine or a mixed primary series (one dose of the Novavax Nuvaxovid vaccine and one dose of another COVID-19

vaccine). If receiving a mixed primary series with the Novavax Nuvaxovid vaccine, informed consent should include a discussion of the benefits and potential risks given the currently limited data on mixed schedules with the Novavax Nuvaxovid vaccine.

- The Novavax Nuvaxovid COVID-19 vaccine may be offered as a booster dose to people who are not able to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. This recommendation is off-label, as the Novavax Nuvaxovid COVID-19 vaccine is not currently authorized for use as a booster dose in Canada. Informed consent should include a discussion about what is known and unknown about the benefits and potential risks of the use of the Novavax Nuvaxovid vaccine as a booster dose, including the off-label status of this recommendation.
- Additional guidance on options and considerations of preferred vaccine types for certain populations, as well as guidance on the use of the Novavax Nuvaxovid COVID-19 vaccine as a booster dose are outlined in the full statement.
- NACI will continue to monitor the evidence on this vaccine as it emerges, including safety and effectiveness data from the real world use of the vaccine, and will update guidance as needed.

For the full statement, please see [NACI Statement: Recommendations on the use of the Novavax Nuvaxovid COVID-19 vaccine.](#)

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 website](#).

QUOTES

“NACI is pleased to see another vaccine product added to Canada’s COVID-19 vaccine portfolio. NACI continues to preferentially recommend mRNA COVID-19 vaccines due to their well-known safety profiles and the excellent protection they provide. However, the Novavax Nuvaxovid COVID-19 vaccine is now an option for people who have not yet been vaccinated against COVID-19 and cannot, or do not want to, receive an mRNA vaccine. The Committee will continue to monitor the evidence on this vaccine as it emerges, including data on the use of the vaccine after the clinical trials and the protection the vaccine offers against the Omicron variant, and will update guidance as needed.”

- Dr. Robyn Harrison, NACI Vice-chair

“Receiving a primary COVID-19 vaccine series is important to protect yourself against severe illness and complications from COVID-19 infection. The Novavax Nuvaxovid vaccine is the first recombinant protein subunit COVID-19 vaccine to be authorised for use in adults in Canada. Recombinant protein subunit vaccine technology, used for the prevention of other vaccine preventable diseases in Canada, offers a COVID-19 vaccine option for those who have been unable to receive an mRNA COVID-19 vaccine due to contraindications or who have not wanted to receive an mRNA COVID-19 vaccine. While clinical trials showed the vaccine provides very good protection against COVID-19, the duration of protection is not yet known and there is currently no data on the efficacy or effectiveness of the vaccine against the Delta or Omicron variants, which emerged following the clinical trials. As with all vaccines, PHAC, Health Canada and NACI will continue to monitor the safety and effectiveness of the Novavax Nuvaxovid COVID-19 vaccine and will update guidance as necessary to provide Canadians with the most up to date information and advice.”

- Dr. Theresa Tam, Chief Public Health Officer