



SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF MARCH 11, 2022

Recommendations on the use of
Medicago COVID-19 vaccine (Covifenz)



OVERVIEW

- On February 24, 2022, Health Canada authorized the Medicigo Covifenz COVID-19 vaccine for use as a primary series in people 18 to 64 years of age. This is the first plant-based virus-like particle (VLP) vaccine authorized for use in Canada.
- On March 11, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) on the use of the Medicigo Covifenz COVID-19 vaccine. These recommendations are based on current scientific evidence and NACI's expert opinion.
- Clinical trials show the Medicigo Covifenz COVID-19 vaccine has a good safety profile and is efficacious (71%) at preventing confirmed symptomatic COVID-19 disease in the short term, prior to the circulation of Omicron. This vaccine is an option for people who have been unable or unwilling to receive an mRNA COVID-19 vaccine. As always, NACI will continue to monitor the emerging evidence as this vaccine is used more widely.
- **For a primary series:**
 - **NACI continues to preferentially recommend that a complete primary series of an mRNA COVID-19 vaccine (Pfizer-BioNTech Comirnaty or Moderna Spikevax) *should be offered* to individuals in the authorized age group without contraindications to the vaccine.**
 - **NACI recommends that a complete primary series of an authorized recombinant protein subunit COVID-19 vaccine (Novavax Nuvaxovid) or a virus-like particle COVID-19 vaccine (Medicago Covifenz) *may be offered* to individuals in the authorized age group without contraindications to the vaccine who are unable or unwilling to receive an mRNA 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 is outlined in the full statement.

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

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

- On February 24, 2022, Health Canada authorized the Medicago Covifenz COVID-19 vaccine for use as a two-dose primary series in people 18 to 64 years of age. This is the first plant-based virus-like particle (VLP) vaccine authorized for use in Canada.
- When developing these recommendations, NACI reviewed clinical trial data on the safety, efficacy, and immune response generated by the Medicago Covifenz COVID-19 vaccine, as well as ethical considerations on the use of the Medicago Covifenz COVID-19 vaccine in the current context of the pandemic.
- Clinical trial data available to date show that the Medicago Covifenz COVID-19 vaccine is efficacious (71%) at 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 of the vaccine against the Omicron variant, as clinical trials were conducted before the emergence of the Omicron variant.
- Side effects, including headache and muscles aches, were typically mild and resolved within one to three days. No serious safety concerns related to the Medicago Covifenz COVID-19 vaccine were identified in clinical trials. In general, clinical trials are too small to detect the risk of rare and very rare safety events.
- NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people due to the very good protection they provide 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 Medicago Covifenz COVID-19 vaccine is a new COVID-19 vaccine option for people who have been unable, due to contraindications, or unwilling to receive an mRNA COVID-19 vaccine.
- People may receive 2 doses of the Medicago Covifenz COVID-19 vaccine or a mixed primary series (1 dose of the Medicago Covifenz COVID-19 vaccine and 1 dose of another COVID-19 vaccine), at the discretion of a healthcare provider.
- If receiving a mixed primary series with the Medicago Covifenz COVID-19 vaccine, informed consent should include a discussion of the benefits and potential risks given the absence of data on mixed schedules with the Medicago Covifenz COVID-19 vaccine.
- Medicago Covifenz is not authorized for use as a booster dose in Canada at this time. Clinical trials evaluating a booster dose of Medicago Covifenz are planned. NACI will assess the evidence on the use of Medicago Covifenz as a booster dose as it becomes available and will provide guidance as needed.
- Informed consent when administering a Medicago Covifenz primary series should include a discussion that Medicago Covifenz is not currently authorized for use as a

booster dose. There are currently no data on Medicago Covifenz as a booster dose, as part of a homologous or heterologous schedule.

- Additional guidance on options and considerations of preferred vaccine types for certain populations is outlined in the full statement.
- NACI will continue to monitor the evidence on the Medicago Covifenz COVID-19 vaccine, including safety and effectiveness data from the real world use of the vaccine, as it emerges and will update guidance and recommendations as needed.

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

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

“NACI has reviewed the available evidence on the newly authorized Medicago Covifenz COVID-19 vaccine. Clinical trials have shown that this vaccine has a good safety profile and can prevent symptomatic COVID-19 disease, which makes it another option for people who have not yet been vaccinated against COVID-19 and who are unable or unwilling to receive an mRNA vaccine. The Committee continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people because of their well-known safety profiles and the large amount of evidence that shows they provide excellent protection against severe COVID-19 outcomes. As with all COVID-19 vaccines, NACI will continue to monitor the evidence on the safety and effectiveness of the Medicago Covifenz vaccine as it is rolled out in public health immunization programs. The Committee will update recommendations if needed to ensure NACI continues to provide up to date guidance for immunization program and policy planners across the country.”

- Dr. Robyn Harrison, NACI Vice-chair

“I am pleased to see the first COVID-19 vaccine developed by a Canadian-based company added to Canada's COVID-19 vaccine portfolio. The authorization of the Medicago Covifenz vaccine provides another COVID-19 vaccine option for adults who have not yet been immunized against COVID-19 and who are unable or unwilling to receive an mRNA COVID-19 vaccine. We know from clinical trials that the Medicago vaccine has a good safety profile and provides protection against symptomatic COVID-19 disease. As with all vaccines, PHAC, Health Canada and NACI will continue to monitor the safety and effectiveness of the Medicago vaccine as it is used more widely. I would like to thank NACI for continuing to provide expert and timely guidance on the use of COVID-19 vaccines in Canada. I encourage anyone who has not yet received a primary series of COVID-19 vaccines to get theirs now.”

- Dr. Theresa Tam, Chief Public Health Officer