NUVAXOVID® is the only protein-based COVID-19 vaccine[1]*

AVAILABLE IN CANADA THIS FALL

ARE YOUR PATIENTS ASKING ABOUT COVID-19 VACCINE OPTIONS?

GIVE PATIENTS A NEW CHOICE FOR COVID-19 VACCINE

NUVAXOVID®

NUVAXOVID® COVID-19 Vaccine (Recombinant protein, Adjuvanted) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

NUVAXOVID® COVID-19 Vaccine (Recombinant protein, Adjuvanted) has been issued marketing authorization with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and effectiveness of the vaccine.

Patients should be advised of the nature of the authorization. For further information for NUVAXOVID® COVID-19 Vaccine (Recombinant protein, Adjuvanted) please refer to Health Canada's COVID-19 vaccines and transfer portal.

*Comparative clinical significance is unknown.

YEARS ON, COVID-19 CONTINUES TO BE A PUBLIC HEALTH CONCERN[2,3]

COVID-19 can cause mild-to-severe illness, and it continued to be the largest driver of hospitalizations for vaccine-preventable respiratory diseases in 2024[2,4]:

>40%
of vaccine-preventable hospitalizations were related to COVID-19[4*]

COVID-19 activity has been shown to increase in late spring/summer and was consistently higher from September to January based on the past 3 surveillance periods (2022-23 to 2024-25)[2]

1,028 total deaths from COVID-19 in Canada from August 2025 to June 2026[3†]

Data for NUVAXOVID® and its effects on vaccine efficacy are presented elsewhere in this piece. The effects of NUVAXOVID® on hospitalizations and deaths have not been evaluated as predefined endpoints in prospectively designed, well-controlled, randomized trials.

*In 2024, there were about 57,700 hospitalizations in Canada for vaccine-preventable respiratory diseases.
†Reported by participating provinces and territories between August 24, 2025 and June 26, 2026.

CONSIDER NUVAXOVID®

The only protein-based COVID-19 vaccine[1]*

Protein-based

NUVAXOVID® directly provides the spike (S) protein to elicit B- and T-cell immune responses[1†]

Spike protein-specific immune response

NUVAXOVID® is composed of purified full-length SARS-CoV-2 recombinant S protein nanoparticle and adjuvant, which enhance the magnitude of the S protein-specific immune response[1,5†]

Ready to use

NUVAXOVID ® is available in prefilled syringes, no freezing or thawing needed.[1]

- Store prefilled syringes between 2°C to 8°C (36°F to 46°F) for a maximum of 6 months. Keep in the outer carton to protect from light.[1]

Please see the NUVAXOVID® Product Monograph for complete information on dosing and administration.

See the efficacy data and tolerability profile of NUVAXOVID®

The safety and effectiveness of NUVAXOVID® for individuals 12 years of age and older are based on data from studies which evaluated the booster vaccination with NUVAXOVID® XBB.1.5 (NVX-CoV2601) vaccine and the primary series and booster vaccination with NUVAXOVID® (Original, Wuhan strain) vaccine, and supported by a study of a booster dose of an investigational vaccine targeting the Omicron BA.5 variant of SARS-CoV-2 in individuals 18 years of age and older, and by a study of a booster dose of an investigational vaccine targeting the Omicron BA.1 variant of SARS-CoV-2 in individuals 18 to 64 years of age.[1]

*Comparative clinical significance is unknown.
†Clinical significance is unknown.

Nuvaxovid®
COVID-19 Vaccine
(Recombinant, Adjuvanted)

DEMONSTRATED POWERFUL PROTECTION AGAINST COVID-19

NUVAXOVID® demonstrated **powerful protection** against COVID-19[1]

Studied in two Phase 3 pivotal trials evaluating efficacy and safety in a combined ~39,000 patients aged 18 and older. Patients received 2 doses of either NUVAXOVID® (Original, Wuhan strain) or placebo. Primary endpoint was efficacy in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 from 7 days after the second dose.[1]

Efficacy of NUVAXOVID® in preventing COVID-19 in PREVENT-19 and UK Studies (primary endpoint; PP-EFF analysis set)[1,6,7]

PREVENT-19 Study (N=25,452):
90.4% vaccine efficacy (95% CI 82.9, 94.6; *p*<0.001)

- COVID-19 Cases: **14/17,312 (0.1%)** with NUVAXOVID® vs. **63/8,140 (0.8%)** with placebo
- Mean Disease Incidence Rate Per Year Per 1,000 People: **3.26** with NUVAXOVID® vs. **34.01** with placebo

UK Study (N=14,039):
89.7% vaccine efficacy (95% CI: 80.2, 94.6)

- COVID-19 cases: **10/7,020 (0.1%)** with NUVAXOVID® vs. **96/7,019 (1.4%)** with placebo
- Mean Disease Incidence Rate Per Year Per 1,000 People: **6.53** with NUVAXOVID® vs. **63.43** with placebo

PREVENT-19 (2019nCoV-301) Study Design[1,6]
An ongoing Phase 3, multi-centre, randomized, observer-blinded, placebo-controlled clinical trial evaluating efficacy and safety in 29,949 adults aged 18 and older in the United States and Mexico. Primary endpoint was efficacy in preventing PCR-confirmed symptomatic mild, moderate, or severe COVID-19 from 7 days after the second dose (90.4%) (95% CI: 82.9, 94.6; *p*<0.001) (N=25,452). Participants were stratified by age (18 to 64 years and ≥65 years) and assigned in a 2:1 ratio to receive 2 doses of NUVAXOVID® (Original, Wuhan strain) or placebo 21 days apart. Data was based on strains circulating at time of study. Moderate disease was defined as fever and evidence of lower respiratory tract infection. Severe disease was defined as clinically significant tachypnea, tachycardia, or hypoxia; receipt of intensive respiratory support; major dysfunction of one or more organ systems; admission to an intensive care unit; or death.

UK (2019nCoV-302) Study Design[1,7]
An ongoing Phase 3, multi-centre, randomized, observer-blinded, placebo-controlled study conducted in 15,187 patients aged 18 and older in the United Kingdom. Primary endpoint was virologically confirmed mild, moderate, or severe COVID-19 infection with an onset at least 7 days after the second injection in patients who were serologically negative at baseline (89.7%) (95% CI: 80.2, 94.6) (N=14,039). Patients were stratified by age (18 to 64 years; 65 to 84 years) to receive 2 doses of NUVAXOVID® (Original, Wuhan strain) or placebo 21 days apart. Data based on strains circulating at time of study.

PP-EFF=Per-Protocol Efficacy.

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NUVAXOVID®: AN ESTABLISHED TOLERABILITY PROFILE

NUVAXOVID® was **generally well tolerated** in clinical trials[1]

The safety profile of NUVAXOVID® (Original, Wuhan strain) was evaluated from an interim analysis of pooled data from 3 clinical trials conducted in the United Kingdom (Study 1), the United States and Mexico (Study 2), and South Africa (Study 3). At the time of the analysis, a total of 48,698 patients aged 18+ received at least one dose of NUVAXOVID® (Original, Wuhan strain) or placebo. The safety profile was also evaluated in an ongoing Phase 3 multicentre, randomized, observer-blinded, placebo-controlled study (Study 2019nCoV-301) in which 12,738 participants received an open-label booster dose of the vaccine at least 6 months after the 2-dose primary series.[1]

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NUVAXOVID®: AN ESTABLISHED TOLERABILITY PROFILE

- 48,000+ patients were evaluated across 3 clinical trials[1]
- **The majority of adverse reactions were mild-to-moderate in severity[1]***

Of the pooled reactogenicity data, which includes participants ≥18 years of age who received at least one dose of NUVAXOVID® (Original, Wuhan strain) (n=21,395) or placebo (n=12,197), the most frequent adverse reactions were injection site tenderness (68%), injection site pain (56%), fatigue (45%), myalgia (44%), headache (41%), malaise (35%), arthralgia (20%), and nausea/vomiting (11%).[1]

The safety and effectiveness of NUVAXOVID® for individuals 12 years of age and older are based on data from studies which evaluated the booster vaccination with NUVAXOVID® XBB.1.5 (NVX-CoV2601) vaccine and the primary series and booster vaccination with NUVAXOVID® (Original, Wuhan strain) vaccine, and supported by a study of a booster dose of an investigational vaccine targeting the Omicron BA.5 variant of SARS-CoV-2 in individuals 18 years of age and older, and by a study of a booster dose of an investigational vaccine targeting the Omicron BA.1 variant of SARS-CoV-2 in individuals 18 to 64 years of age.[1]

*Median duration was ≤2 days for local events and ≤1 day for systemic events.[1]

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IMPORTANT SAFETY INFORMATION

Clinical use:

The safety and effectiveness of NUVAXOVID® for individuals 12 years of age and older are based on data from studies which evaluated the booster vaccination with NUVAXOVID® XBB.1.5 (NVX-CoV2601) vaccine and the primary series and booster vaccination with NUVAXOVID® (Original, Wuhan strain) vaccine, and supported by a study of a booster dose of an investigational vaccine targeting the Omicron BA.5 variant of SARS-CoV-2 in individuals 18 years of age and older, and by a study of a booster dose of an investigational vaccine targeting the Omicron BA.1 variant of SARS-CoV-2 in individuals 18 to 64 years of age.

Pediatrics: Clinical studies of NUVAXOVID® (Original, Wuhan strain) included participants ≥12 years of age to <18 years of age and their data contributes to the overall assessment of safety and effectiveness of NUVAXOVID® in this pediatric population.

Geriatrics: Clinical studies of NUVAXOVID® (Original, Wuhan strain) and NUVAXOVID® XBB.1.5 and an investigational vaccine targeting the Omicron BA.5 variant of SARS-CoV-2 include participants 65 years of age and older, and their data contribute to the overall assessment of the safety and effectiveness of NUVAXOVID®.

Relevant warning and precautions:

- Individuals suffering from an acute severe febrile illness or acute infection
- Vaccination with NUVAXOVID® may not protect all recipients
- Acute allergic reactions
- Cardiovascular, including myocarditis and pericarditis
- Caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder
- Driving and operating machinery
- Unknown impact on fertility
- Diminished immune response
- Syncope
- Pregnancy and nursing women
- Pediatrics
- Geriatrics

For more information:

Please consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00084074.PDF for important information relating to adverse reactions, interactions and dosing information. The Product Monograph is also available by calling 1-800-265-7927.

Nuvaxovid®
COVID-19 Vaccine
(Recombinant, Adjuvanted)

THE ONLY PROTEIN-BASED COVID-19 VACCINE[1]*

NUVAXOVID®

DEMONSTRATED POWERFUL PROTECTION. GENERALLY WELL TOLERATED.[1]

CHOOSE NUVAXOVID® FOR YOUR PATIENTS' ROUTINE, SEASONAL COVID-19 PROTECTION

90.4%
Vaccine efficacy demonstrated vs. placebo in the PREVENT-19 Study (14/17,312 cases vs. 63/8,140 cases, respectively; $p<0.001$)[1,6]

89.7%
Vaccine efficacy demonstrated vs. placebo in the UK Study (10/7,020 cases vs. 96/7,019 cases, respectively; 95% CI: 80.2, 94.6)[1,7]

Well-established tolerability profile demonstrated across clinical trials[1]

Ready-to-use prefilled syringes[1]

Learn more about how to protect your patients with NUVAXOVID®

*Comparative clinical significance is unknown.

References:

1. NUVAXOVID® Product Monograph. Sanofi Vaccines Canada Ltd., March 6, 2026. **2.** Public Health Agency of Canada. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI): Guidance on the use of COVID-19 vaccines starting fall 2026. Published June 2026. https://publications.gc.ca/collections/collection_2026/aspc-phac/HP40-376-2026-eng.pdf. **3.** Government of Canada. COVID-19: Canadian respiratory virus surveillance report. June 26, 2026. Accessed July 22, 2026. https://health-infobase.canada.ca/respiratory-virus-surveillance/covid-19.html. **4.** Canadian Institute for Health Information. Public health prevents diseases and makes health care systems more resilient. April 16, 2026. Accessed May 06, 2026. https://www.cihi.ca/en/priority-indicators-for-public-health-systems-in-canada/interconnection-with-health-care-systems. **5.** Government of Canada. COVID-19 vaccines: Canadian Immunization Guide. Updated September 2025. Accessed April 9, 2026. https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html. **6.** Dunkle LM, Kotloff KL, Gay CL, *et al.* Efficacy and safety of NVX-CoV2373 in adults in the United States and Mexico. *N Engl J Med.* 2022;386(6):531-543. doi:10.1056/NEJMoa2116185. **7.** Heath PT, Galiza EP, Baxter DN, *et al.* Safety and efficacy of NVX-CoV2373 Covid-19 vaccine. *N Engl J Med.* 2021;385(13):1172-1183. doi:10.1056/NEJMoa2107659

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REVIEWED BY PAAB

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