Now updated for the fall season

Choose the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula)

The only non-mRNA COVID-19 vaccine built with protein[1]

Vial is not actual size.

EUA Statement

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) for use in individuals 12 years of age and older.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. Individuals previously vaccinated with any COVID-19 vaccine: A single dose is administered at least 2 months after receipt of the last previous dose of COVID-19 vaccine. Individuals not previously vaccinated with any COVID-19 vaccine: Two doses are administered 3 weeks apart.

Please see Important Safety Information on pages 2-3 and the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information provided by the Novavax representative.

IMPORTANT SAFETY INFORMATION

The safety data for Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) are based on studies of the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) [no longer authorized for use in the U.S.] and of the Novavax monovalent vaccine (Omicron BA.1); bivalent vaccine (Original and Omicron BA.1); bivalent vaccine (Original and Omicron BA.5); and monovalent vaccine (Omicron BA.5) [none of which has been authorized or approved in the U.S.].

Contraindications

Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted, or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Novavax COVID-19 Vaccine, Adjuvanted.

Warnings and Precautions

Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted.

Monitor Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis: Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of the Novavax COVID-19 Vaccine, Adjuvanted *(see Full EUA Fact Sheet)*.
The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis).
Syncope (fainting): May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.
Limitations of Vaccine Effectiveness: The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

Please see additional Important Safety Information on the next page.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis.

Myocarditis, pericarditis, anaphylaxis, paresthesia, and hypoesthesia have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

Required Reporting for Adverse Events and Vaccine Administration Errors

Vaccination providers must report the events listed below following administration of the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events (irrespective of attribution to vaccination),
- cases of myocarditis,
- cases of pericarditis,
- cases of Multisystem Inflammatory Syndrome (MIS)
- cases of COVID-19 that results in hospitalization or death

Complete and submit reports to VAERS online: https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) EUA" in the description section of the report.

To the extent feasible, report adverse events to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: www.NovavaxMedInfo.com, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

Please see the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information provided by the Novavax representative.

Offer protection with the protein-based Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula)[1]

The Novavax COVID-19 vaccine was studied globally in approximately 45,000 participants

In a phase 3 clinical trial, the vaccine met the primary endpoint and **demonstrated efficacy in preventing symptomatic mild, moderate, or severe COVID-19** from 7 days after dose 2:

Primary endpoint: vaccine efficacy against COVID-19

Adults aged 18 years or older

(95% CI: 83.8, 94.3)
N=25,657

Adolescents aged 12 to 17 years

(95% CI: 37.6, 92.5)
N=1,799

Note: Data based on strains circulating at the time of the study.

The effectiveness of the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is based on the effectiveness of the Novavax COVID-19 vaccine (original monovalent) and the immunogenicity of the monovalent vaccine (Omicron BA.1) and the monovalent vaccine (Omicron BA.5).[1]

Secondary endpoints

Secondary endpoints among adult clinical trial participants

Protection against moderate-to-severe disease from then-circulating strains of virus[2]*

(95% CI: 87.0, 100.0)
N=25,452

Protection against COVID-19 in high-risk patients[2]*†

(95% CI: 83.6, 95.0)
N=24,230

The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients[1]

*Moderate COVID-19 was defined as high fever and objective 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.[2]

†Participants were classified as having a high risk of severe COVID-19 if they had 1 or more of the following coexisting conditions: obesity (defined as a body mass index [BMI] of ≥30.0), chronic lung disease, diabetes mellitus type 2, cardiovascular disease, or chronic kidney disease.[2]

Post hoc analysis

In a phase 3 trial analyzing COVID-19 hospitalizations, 4 hospitalizations were identified—0 among Novavax COVID-19 vaccine recipients and 4 among placebo—resulting in a vaccine efficacy against hospitalization of 100% (95% CI: 28.8, 100.0).[3]

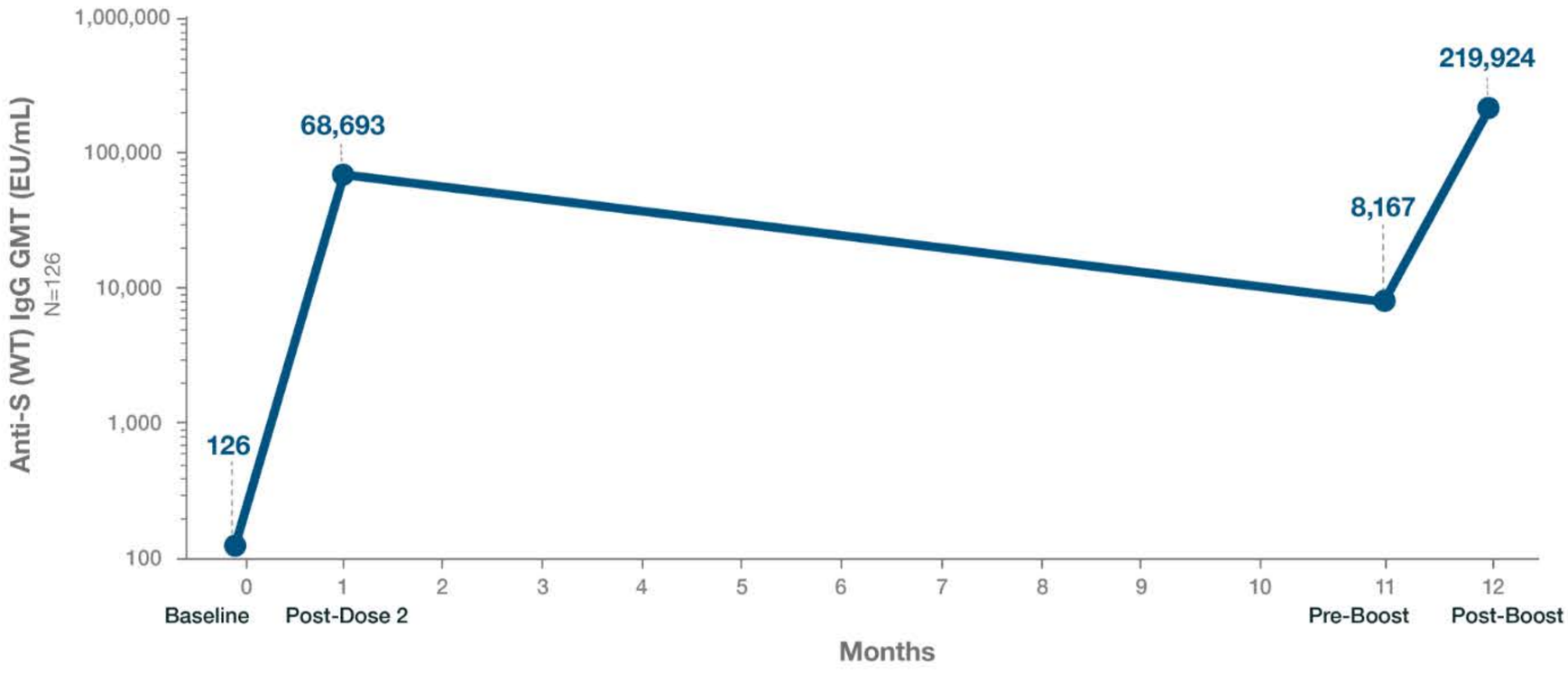
- Limitations include vaccine efficacy estimates impacted by a low number of events (ie, hospitalizations), pandemic-era restrictions successfully reducing infections and hospitalizations during the study, and the exclusion of key demographics, such as participants with certain underlying health conditions[3]

100%

(95% CI: 28.8, 100.0)
N=25,482

Efficacy against hospitalization due to then-circulating strains of virus[3]

In a follow-up to the phase 3 trial, participants who completed the primary vaccination series had antibodies that remained elevated at 11 months[4,5]



Anti-S (WT) IgG GMT=anti-spike (wild type) immunoglobulin G geometric mean titer.

In this follow-up evaluation before the booster dose, it was predetermined that participants who received the primary vaccination series pre-crossover would receive a Novavax COVID-19 Vaccine, Adjuvanted booster at the 11-month mark. Those who received placebo pre-crossover were not included in this analysis. The 11-month antibody levels were based on evaluation of anti-prototype spike antibodies to the Novavax COVID-19 vaccine.

Please see Important Safety Information on pages 2-3 and the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information provided by the Novavax representative.

Help increase your patients' protection this year with a protein-based vaccine[1]

Ages 18 years and older

A booster response with the Novavax COVID-19 Vaccine, Adjuvanted was observed in a phase 3 clinical trial with neutralizing antibodies 3.4x higher than after the primary series

Geometric mean titer (GMT) ratio of neutralizing antibody titers (MN_{50}) against the original SARS-CoV-2 strain at 28 days after a booster dose vs 14 days after primary series

- The analysis of the GMT ratio of MN_{50} following the booster dose vs the primary series met the noninferiority criteria for a booster response (lower limit of the 95% CI >0.67 and point estimate >0.83)
- The lower limit of the two-sided 95% CI for the difference in seroconversion rate (SCR) of the booster dose vs primary series was -14.4%, which did not meet the noninferiority criteria for a booster response (lower limit of 95% CI for the percentage difference of ≥-10%)
- An additional post hoc analysis evaluated SCR using baseline MN_{50} prior to dose 1 of the primary series. The booster dose SCR, with seroconversion defined as at least a 4-fold rise relative to the time of first dose, was 98.3%. The difference in SCR among 239 participants in this post hoc analysis who had immunogenicity data (microneutralization) available for both the booster and primary series was 3.8% (95% CI: 2.0, 7.0)

Note: The median duration between the time of the second dose of the Novavax COVID-19 vaccine and the time of the booster dose was 10 months.

Please see Important Safety Information on pages 2-3 and the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information provided by the Novavax representative.

Ages 12-17 years

A booster response with the Novavax COVID-19 Vaccine, Adjuvanted was observed in a phase 3 clinical trial with neutralizing antibodies 2.7x higher than after the primary series[1]

Geometric mean titer (GMT) ratio of neutralizing antibody titers (MN_{50}) against the original SARS-CoV-2 strain at 28 days after a booster dose vs 14 days after primary series

- The analysis of the GMT ratio of MN_{50} following the booster dose vs the primary series met the noninferiority criteria for a booster response (lower limit of the 95% CI >0.67 and point estimate >0.83)
- The lower limit of the two-sided 95% CI for the difference in seroconversion rate (SCR) of the booster dose vs primary series was -6.8%, which met the noninferiority criteria for a booster response (lower limit of 95% CI for the percentage difference of ≥-10%)

Note: The median duration between the time of the second dose of the Novavax COVID-19 vaccine and the time of the booster dose was 10.6 months.

Study designs[1]

Primary series

The phase 3 clinical study is a multicenter, randomized, observer-blinded, placebo-controlled study conducted in the United States and Mexico. Upon enrollment, participants were stratified by age (18 to 64 years; ≥65 years) and randomized in a 2:1 ratio to receive the Novavax COVID-19 Vaccine, Adjuvanted or placebo. Participants 12 to 17 years of age were included in the expansion trial.

Inclusion criteria: Participants with clinically stable underlying comorbidities were included, as well as those with well-controlled HIV.

Exclusion criteria: Participants were excluded if they were significantly immunocompromised due to immunodeficiency disease or on chemotherapy for active cancer, had received chronic immunosuppressive therapy or received immunoglobulin or blood-derived products within 90 days, were pregnant or breastfeeding, and/or had a history of laboratory-confirmed, diagnosed COVID-19.

Booster

The open-label booster phase of this study included participants 18 years and older in the United States and Mexico and participants 12 to 17 years of age in the United States, who received a single booster dose of the Novavax COVID-19 vaccine. Participants aged 18 years of age and older received a booster at least 6 months after completion of the primary series and participants 12 to 17 years of age received a booster at least 5 months after completion of the primary series.

Prespecified immunogenicity noninferiority analyses included an assessment of GMT ratio of MN_{50} and difference in SCR. Seroconversion for a participant was defined as achieving a 4-fold rise in MN_{50} from baseline (before the booster dose and before the first dose of the primary series).

Safety profile—primary series[1]

Ages 18-64 years

Solicited local and systemic adverse reactions starting within 7 days* after each dose of the vaccine in participants 18 to 64 years of age†

Event (any grade)	Novavax COVID-19 Vaccine, Adjuvanted		Placebo	
	Dose 1 n=15,884	Dose 2 n=15,148	Dose 1 n=7,868	Dose 2 n=7,361
Local adverse reactions, %				
Pain/tenderness	60.5	80.8	21.7	22.0
Redness	1.0	6.9	0.3	0.4
Swelling	0.9	6.2	0.3	0.3
Systemic adverse reactions, %				
Fever	0.4	6.2	0.4	0.2
Headache	26.2	47.1	23.7	20.3
Fatigue/malaise	30.8	58.3	26.6	25.7
Muscle pain	24.1	50.7	13.6	12.2
Joint pain	7.9	23.4	6.6	6.8
Nausea or vomiting	6.7	12.0	5.9	5.7

*Seven days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain †medication were collected in an electronic diary (eDiary).

Solicited safety set includes participants who received at least 1 dose of study vaccine and who completed their eDiary.

The safety data accrued with the Novavax COVID-19 Vaccine, Adjuvanted (original monovalent) [no longer authorized for use in the U.S.] and from studies of Novavax's adjuvanted monovalent COVID-19 vaccine (Omicron BA.1), Novavax's adjuvanted monovalent COVID-19 vaccine (Omicron BA.5), Novavax's adjuvanted bivalent vaccine (original and Omicron BA.1) and Novavax's adjuvanted bivalent vaccine (original and Omicron BA.5), none of which have been authorized in the US, are relevant to the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) because these vaccines are manufactured using a similar process.[1]

Safety profile—booster[1]

Ages ≥18 years

Solicited local and systemic adverse reactions starting within 7 days* after a booster dose of the vaccine in participants 18 years of age and older†

Event (any grade)	**Novavax COVID-19 Vaccine, Adjuvanted** n=238
Local adverse reactions, %	
Pain/tenderness	81.1
Redness	6.3
Swelling	8.4
Systemic adverse reactions, %	
Fever	6.3
Headache	52.9
Fatigue/malaise	63.4
Muscle pain	63.0
Joint pain	30.3
Nausea or vomiting	14.7

*Seven days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in an electronic diary (eDiary).

†The analysis included a total of 238 participants who received the booster dose and who completed their eDiary.

Omicron BA.5 booster safety +

Omicron BA.5 booster safety[1]

The safety data accrued with the Novavax COVID-19 Vaccine, Adjuvanted (original monovalent) [no longer authorized for use in the U.S.] and from studies of Novavax's adjuvanted monovalent COVID-19 vaccine (Omicron BA.1), Novavax's adjuvanted monovalent COVID-19 vaccine (Omicron BA.5), Novavax's adjuvanted bivalent vaccine (original and Omicron BA.1) and Novavax's adjuvanted bivalent vaccine (original and Omicron BA.5), none of which have been authorized in the US, are relevant to the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) because these vaccines are manufactured using a similar process.[1]

The safety of the Novavax COVID-19 Vaccine, Adjuvanted (original monovalent), monovalent vaccine (Omicron BA.1), the bivalent vaccine (original and Omicron BA.1), the monovalent vaccine (Omicron BA.5), and the bivalent vaccine (original and Omicron BA.5) booster dose in individuals who received 3 or more doses of mRNA vaccines was studied in a 2-part randomized, observer-blinded study conducted to evaluate the safety and immunogenicity of Novavax COVID-19 vaccines in adults previously vaccinated with other COVID-19 mRNA vaccines. The original monovalent, the monovalent vaccine (Omicron BA.1), and the bivalent vaccine (original and Omicron BA.1) groups included individuals 18 to 64 years of age. The monovalent vaccine (Omicron BA.5) and the bivalent vaccine (original and Omicron BA.5) groups included individuals 18 years of age and older.[1]

Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information provided by the Novavax representative.

Safety profile—booster[1]

Ages 12-17 years

Solicited local and systemic adverse reactions starting within 7 days* after a booster dose of the vaccine in participants 12 to 17 years of age†

Event (any grade)	Novavax COVID-19 Vaccine, Adjuvanted n=190
Local adverse reactions, %	
Pain/tenderness	80.5
Redness	10.5
Swelling	10.0
Systemic adverse reactions, %	
Fever	23.2
Headache	13.2
Fatigue/malaise	69.5
Muscle pain	61.6
Joint pain	22.6
Nausea or vomiting	2.6

*Seven days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in an electronic diary (eDiary).

†The analysis included a total of 190 participants who received the booster dose and who completed their eDiary.

Safety profile—primary series[1]

Ages ≥65 years

Solicited local and systemic adverse reactions starting within 7 days* after each dose of the vaccine in participants 65 years of age and older†

Event (any grade)	Novavax COVID-19 Vaccine, Adjuvanted		Placebo	
	Dose 1 n=2,251	Dose 2 n=2,048	Dose 1 n=1,114	Dose 2 n=978
Local adverse reactions, %				
Pain/tenderness	37.9	61.4	15.7	16.5
Redness	0.7	4.8	0.4	0.4
Swelling	0.8	5.4	0.09	0.4
Systemic adverse reactions, %				
Fever	0.4	2.0	0.3	0.7
Headache	15.3	24.5	16.5	14.7
Fatigue/malaise	19.7	34.9	18.1	18.6
Muscle pain	12.6	27.4	11.2	10.4
Joint pain	6.2	13.2	6.4	6.4
Nausea or vomiting	3.6	5.3	2.9	3.6

*Seven days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in an electronic diary (eDiary).

†Solicited safety set includes participants who received at least 1 dose of study vaccine and who completed their eDiary.

Safety profile—primary series[1]

Ages 12-17 years

Solicited local and systemic adverse reactions starting within 7 days* after each dose of the vaccine in participants 12 to 17 years of age†

Event (any grade)	Novavax COVID-19 Vaccine, Adjuvanted		Placebo	
	Dose 1 n=1,448	Dose 2 n=1,394	Dose 1 n=726	Dose 2 n=686
Local adverse reactions, %				
Pain/tenderness	65.3	75.0	28.1	20.6
Redness	1.0	7.5	0.7	0
Swelling	1.4	8.0	0.4	0.1
Systemic adverse reaction, %				
Fever	0.8	16.9	0.7	0.1
Headache	30.4	56.9	24.9	17.3
Fatigue/malaise	28.9	57.9	19.6	16.5
Muscle pain	34.0	49.0	15.7	12.0
Joint pain	7.0	16.2	4.8	3.1
Nausea or vomiting	7.8	19.9	7.7	4.8

*Seven days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in an electronic diary (eDiary).

†Solicited safety set includes participants who received at least 1 dose of study vaccine and who completed their eDiary.

One vial, one dosage strength for all authorized uses[1]

Dosing and schedule for patients aged 12 years and older

Previously vaccinated with any COVID-19 vaccine

- The Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is administered intramuscularly as a single 0.5 mL dose at least 2 months after receipt of the last previous dose of a COVID-19 vaccine

Not previously vaccinated with any COVID-19 vaccine

- The Novavax COVID-19 vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 3 weeks apart

Individuals with certain kinds of immunocompromise*

- An additional dose of the Novavax COVID-19 vaccine may be administered at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula)
- Additional doses of the Novavax COVID-19 vaccine may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances
- The timing of the additional doses may be based on the individual's clinical circumstances

*Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Simple storage for convenient vaccination[1,6]

The Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) can be stored unopened for up to 9 months[1,6]

Ready to use—no dilution, mixing, or thawing required.[1]

Store the unpunctured multidose vial in a refrigerator
between 2 and 8 °C (36 and 46 °F) for up to 9 months.[1,6]

Do not freeze. Protect from light.[1]

After first puncture, store the vial between 2 and 25 °C (36 and 77 °F) for up to 12 hours.[1]
Discard the vial 12 hours after the first puncture.

Choose the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula)

A non-mRNA COVID-19 vaccine for pharmacists and healthcare providers who don't want to leave any patients behind[1]

Efficacy

- 90.4% efficacy against COVID-19 in adult clinical trial participants[1]
- 100% protection against moderate-to-severe illness from then-circulating virus strains observed in the clinical trial population[2]*

*Secondary endpoint.[2]

Safety profile

- Demonstrated safety profile evaluated globally in approximately 45,000 adults and adolescents[1]
- Do not administer the vaccine to individuals with a known history of a severe allergic reaction (eg, anaphylaxis) to a previous dose or any component of the vaccine[1]

Dosing and storage

- One vial, one dosage strength for all authorized uses[1]
- Store in a standard refrigerator for up to 9 months[1,6]
- Ready to use with no dilution, mixing, or thawing required[1]

For additional resources, visit https://us-hcp.novavaxcovidvaccine.com/

Order the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) now

To help your patients find a vaccination location, visit vaccines.gov

References: 1. Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) EUA Fact Sheet for Healthcare Providers. Novavax, Inc.; October 2023. **2.** Dunkle LM, Kotloff 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. **3.** Marchese AM, Zhou X, et al. NVX-CoV2373 vaccine efficacy against hospitalization: a post hoc analysis of the PREVENT-19 phase 3, randomized, placebo-controlled trial. *Vaccine*. 2023;41(22):3461-3466. **4.** Añez G, Bennett C. Paving the way for protein: Novavax's COVID-19 vaccine as a booster and variant-adapted. Presented at: World Vaccine Congress Europe; October 12, 2022; Barcelona, Spain. **5.** Data on file A. Novavax, Inc. 2023. **6.** Data on file B. Novavax, Inc. 2023.

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