COVID-19 Vaccine, Adjuvanted (Novavax) (2025-2026 Formula)

AHFS Class: 80:12 — Vaccines (tofc-80)

COVID-19 Vaccine, Adjuvanted (Novavax) (2025-2026 Formula) *(AHFS DI)*

COVID-19 Vaccine, Adjuvanted (2025-2026 Formula)

Alert:

On January 5, 2026, the US Department of Health and Human Services (HHS) announced the approval of a revised US childhood and adolescent immunization schedule (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html (https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html)). Under the revised recommendations, CDC continues to organize the childhood immunization schedule in three distinct categories (Immunizations Recommended for All Children, Immunizations Recommended for Certain High-Risk Groups or Populations, and Immunizations Based on Shared Clinical Decision-Making) but changes individual vaccine placement within those categories. For additional information, see https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html (https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html) .

Introduction

COVID-19 vaccine, adjuvanted (Novavax) is a protein subunit vaccine that contains a severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) recombinant spike protein nanoparticle vaccine with Matrix-M adjuvant.[1,4,10,]

Uses

▪ Prevention of Coronavirus Disease 2019 (COVID-19)

COVID-19 vaccine, adjuvanted (Novavax) is used for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.[1,] The Nuvaxovid® vaccine is FDA-labeled for the prevention of COVID-19 in adults ≥65 years of age and in patients 12—64 years of age who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.[1,] Underlying conditions for which there is evidence indicating a higher risk of experiencing severe outcomes of COVID-19 include asthma, cancer, cerebrovascular disease, chronic kidney disease, certain chronic lung diseases, certain chronic liver diseases, cystic fibrosis, diabetes mellitus, disabilities, heart conditions, HIV, certain mental health conditions, certain neurologic conditions, obesity, physical inactivity, pregnancy or recent pregnancy, primary immunodeficiencies, smoking (current or former), solid organ or blood stem cell transplantation, tuberculosis, and use of corticosteroids (or other immunosuppressive medications).[76,] Previous preparations of COVID-19 vaccine, adjuvanted (Novavax) were available for use under an Emergency Use Authorization (EUA), originally issued on July 13, 2022; however, FDA revoked the EUA on August 27, 2025.[2,3,74,] The current COVID-19 vaccine, adjuvanted has been specifically formulated for the 2025-2026 season and contains recombinant spike (rS) protein of the SARS-CoV-2 Omicron variant lineage JN.1.[1,]

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) has issued recommendations and clinical considerations for the use of COVID-19 vaccines, including dosage and administration, specific populations and situations, and cautionary information.[13,] CDC currently recommends COVID-19 vaccination based on a shared decision-making process between the healthcare provider and the patient or parent/guardian.[80,81,82,83,84,] The decision to administer a COVID-19 vaccine should be individualized with consideration that the risk-benefit of vaccination is most favorable for individuals who are at increased risk for severe COVID-19 disease and lowest for those who are not at increased risk.[81,83,] There are 2 types of COVID-19 vaccines available in the US (mRNA vaccines and a protein subunit vaccine).[13,] An age-appropriate COVID-19 vaccine product should be administered for each dose.[81,83,] ACIP states that there is no preferential recommendation for the use of any one COVID-19 vaccine over another when more than one recommended and age-appropriate vaccine is available.[13,] For additional information, consult the ACIP recommendations at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html)

The American Academy of Pediatrics (AAP) recommends COVID-19 vaccination in infants, children, and adolescents at high risk for severe COVID-19, but also states that children not included in specified high-risk groups whose parent or guardian desires their protection from COVID-19 should be offered a single dose of an age-appropriate 2025-2026 COVID-19 vaccine.[78,] For additional information consult the current AAP policy statement.[78,]

The American College of Obstetricians and Gynecologists (ACOG) provides recommendations for the use of COVID-19 vaccines in individuals who are pregnant (or may become pregnant) or lactating.[16,] ACOG currently recommends that all individuals who are or will be pregnant receive the seasonally updated COVID-19 vaccine booster at any time during pregnancy; the available data support the benefits of vaccination in reducing pregnancy complications and reducing neonatal morbidity and mortality.[16,] Pregnant individuals have historically been at increased risk of severe disease, adverse pregnancy outcomes, and maternal death from COVID-19 infection.[16,] Additionally, vaccination during pregnancy provides passive immunity to infants, protecting them from COVID-19 in the first few months of life before they can be vaccinated.[16,] ACOG states that any of the currently authorized COVID-19 vaccines can be administered to pregnant, recently pregnant, or lactating patients.[16,]

The Center for Infectious Disease Research and Policy (CIDRAP) has established the Vaccine Integrity Project to provide evidence-based guidance on key immunizations for the upcoming respiratory season focusing on influenza, RSV, and COVID.[77,] The Vaccine Integrity Project is an initiative to safeguard vaccine use in the US and disseminate evidence-based information for informed decision-making.[77,] A multi-disciplinary group of experts has been convened to prepare recommendations for the upcoming 2025-2026 fall-winter respiratory season.[77,] CIDRAP will provide updates on the initiative's progress as they become available.[77,] For additional information see, https://www.cidrap.umn.edu/vaccine-integrity-project (https://www.cidrap.umn.edu/vaccine-integrity-project) .

Clinical Experience

Efficacy, safety, and immunogenicity of the current COVID-19 vaccine, adjuvanted (Novavax) (2025-2026 Formula) are based on data accrued with previous formulations of the vaccine (Original monovalent, monovalent Omicron BA.1, monovalent Omicron BA.5, bivalent Original and Omicron BA.1, bivalent Original and Omicron BA.5, monovalent XBB.1.5) that are no longer authorized for use in the US; historic data are provided below on these previous formulations.[1,2,]

Primary Vaccination in Adults 18 Years of Age and Older.

Efficacy, safety, and immunogenicity of COVID-19 vaccine, adjuvanted (Novavax) for the prevention of COVID-19 were evaluated in a multicenter, randomized, observer-blinded, placebo-controlled, phase 3 trial conducted in the US and Mexico (NCT04611802; PREVENT-19) using the original formulation of the vaccine.[1,4,9,] The primary objective of the study was to determine efficacy of a 2-dose primary series of the vaccine compared to placebo in preventing polymerase chain reaction (PCR)-confirmed COVID-19 illness diagnosed ≥7 days after completion of the second dose.[4,9,10,] Eligible participants were medically stable individuals ≥18 years of age who had no known previous laboratory-confirmed SARS-CoV-2 infection.[1,4,9,] Individuals with clinically stable underlying medical conditions including well-controlled human immunodeficiency virus (HIV) infection were eligible; however, the study excluded participants who were significantly immunocompromised due to an immunodeficiency condition, received chronic immunosuppressive therapy or immunoglobulin or blood derived products within 90 days, or had a history of laboratory-confirmed COVID-19.[1,9,] Approximately 95.2% of the study population were at high risk for COVID-19 due to living or working conditions with known frequent exposure to SARS-CoV-2, at least one pre-existing medical condition (chronic lung disease, cardiovascular disease, chronic liver disease, severe obesity, and diabetes), or age ≥65 years.[1,]

Participants were stratified by age (18–64 years of age and ≥65 years of age) and randomized in a 2:1 ratio to receive 2 doses of the Novavax COVID-19 vaccine (Original strain) or placebo given 3 weeks apart.[1,] During the study, COVID-19 vaccines authorized for emergency use became available, and participants were offered the opportunity to cross over from the originally assigned study treatment to the other group (vaccine or placebo) in a blinded fashion.[1,9,]

The primary efficacy analysis population included 25,510 participants who received a two-dose series of either the COVID-19 vaccine, adjuvanted (Novavax) or placebo, did not experience an exclusionary protocol deviation, and did not have evidence of SARS-CoV-2 at baseline or 6 days after the second dose.[1,] The median age of participants was 47 years (range: 18—95 years); 51.6% were male, 75.9% were white, 11.1% were Black or African American, and 21.4% were Hispanic or Latino.[1,] Demographic and baseline characteristics as well as pre-existing medical conditions were similar among participants who received the Novavax COVID-19 vaccine and those who received placebo.[1,] The efficacy of the COVID-19 vaccine, adjuvanted (Novavax) to prevent mild, moderate, or severe COVID-19 was 89.6%.[1,] No cases of moderate or severe COVID-19 were reported in participants who had received the vaccine compared to 8 cases of moderate COVID-19 and 4 cases of severe COVID-19 in participants that received placebo.[1,] Vaccine efficacy was 77.4% in participants of Hispanic/Latino ethnicity and was 93.2% in participants who were not Hispanic/Latino; vaccine efficacy was 68% in participants ≥65 years of age and was 89.2% in participants 50—64 years of age.[1,]

Primary Vaccination in Adolescents 12 Through 17 Years of Age.

Efficacy, safety, and immunogenicity of the COVID-19 vaccine, adjuvanted (Novavax) for the prevention of COVID-19 in adolescents 12—17 years of age is based on a comparison of immune responses in adults 18—25 years of age in an expansion study of PREVENT-19 (NCT04611802).[1,20,] Eligible participants were healthy or medically stable individuals with no history of previous laboratory-confirmed diagnosis of SARS-CoV-2 or COVID-19 prior to randomization.[1,] Individuals with clinically stable underlying medical conditions including well-controlled HIV infection were eligible; however, the study excluded participants who were significantly immunocompromised due to an immunodeficiency disease, received chronic immunosuppressive therapy or immunoglobulin or blood-derived products within 90 days, or had a history of laboratory-confirmed COVID-19.[1,] Participants were randomized in a 2:1 ratio to receive 2 doses of the Novavax COVID-19 vaccine (Original strain) or placebo given 3 weeks apart.[1,]

A total of 2247 participants were randomized; the median age was 14 years, 52.4% were male, 79.8% were white, 11.2% were Black or African American, and 17.2% were Hispanic/Latino.[1,20,] The efficacy of the COVID-19 vaccine, adjuvanted (Novavax) to prevent mild, moderate, or severe COVID-19 (from 7 days after dose 2) was 79.8%.[1,] No cases of moderate or severe COVID-19 were reported in participants who received the vaccine compared to 1 moderate and no severe COVID-19 cases in participants that received placebo.[1,]

Additional Doses in Adults 18 Years of Age and Older.

The effectiveness of a booster dose of the COVID-19 vaccine, adjuvanted (Novavax) in adults ≥18 years of age was evaluated in an open-label, dose phase study of the PREVENT-19 trial.[1,] Participants received a single booster dose of the COVID-19, adjuvanted (Novavax) vaccine at least 6 months after completion of the primary series.[1,] Immunogenicity was evaluated by comparing neutralizing antibody titers following the booster dose compared to titers following the primary series; seroconversion was defined as achieving a 4-fold increase in neutralizing antibody titers compared to baseline (prior to receipt of the vaccine primary series or booster).[1,] A subset of 255 participants were included; the median age was 52 years (range: 19—79 years); 52% were male, 82.7% were white, 9.3% were Black or African American, and 14.7% were Hispanic or Latino.[1,] Of the 222 participants with immunogenicity data available for both time points, the seroconversion rate was 92.3% after the booster dose and 94.1% after the primary series.[1,]

An open-label, single arm study evaluated the immune response of COVID-19 vaccine naïve participants ≥18 years of age who had a clinical history of COVID-19-like disease with immunologic or virologic evidence of prior SARS-CoV-2 infection and no active infection compared to participants who were previously vaccinated (received at least 3 doses of either the COVID-19 vaccine, mRNA [Pfizer-BioNTech] or COVID-19 vaccine, mRNA [Moderna] vaccine).[1,21,22,] All study participants received a single dose of Novavax COVID-19 vaccine, adjuvanted (2023-2024 Formula).[1,21,22,] The primary immunogenicity analysis population included 288 participants who were baseline SARS-CoV-2 seropositive and COVID-19 vaccine naïve and 305 participants who were previously vaccinated.[1,] Among vaccine-naïve participants, the median age was 38 years; 59.4% were female, 50% were white, 43.1% were Black or African American, and 26% were Hispanic or Latino.[1,] Among participants that were

previously vaccinated, the median age was 53 years; 61.6% were female, 75.1% were white, 14.8% were Black or African American, and 19.7% were Hispanic or Latino.[1] Seroresponse was defined as the percentage of participants achieving a 4-fold rise in titer from baseline against a pseudovirus expressing Omicron XBB.1.5 following the single dose of the vaccine.[1] The seroresponse rates were 74.3% and 64.3% in the vaccine-naïve and previously vaccinated participants, respectively.[1]

Additional Doses in Adolescents 12 Through 17 Years of Age.

The effectiveness of a booster dose of the COVID-19 vaccine, adjuvanted (Novavax) in adolescents 12—17 years of age was evaluated in an open-label, dose phase study of the PREVENT-19 trial.[1] Participants received a single booster dose of the COVID-19, adjuvanted (Novavax) vaccine at least 5 months after completion of the primary series.[1] Immunogenicity was evaluated by comparing the neutralizing antibody titers following the booster dose compared to titers following the primary series; seroconversion was defined as achieving a 4-fold increase in neutralizing antibody titers compared to baseline (prior to receipt of the vaccine primary series).[1] A subset of 56 participants were included; the median age was 14 years (range: 12—17 years); 51.8% were male, 91.1% were white, 1.8% were Black or African American, and 17.9% were Hispanic or Latino.[1] The seroconversion rate was 100% after both the primary series and booster dose.[1]

Dosage and Administration

▪ General

Pretreatment Screening

Screen all individuals for contraindications and precautions to vaccination.[1]

Patient Monitoring

Monitor all individuals who receive a COVID-19 vaccine for immediate adverse reactions according to CDC (ACIP) guidelines.[1,13] ACIP states that vaccination providers should consider observing the following individuals for 30 minutes after receiving the vaccine: those with a history of a non-severe, immediate (onset less than 4 hours) allergic reaction to a previous dose of COVID-19 vaccine, and those with a history of a diagnosed non-severe allergy to a component of the COVID-19 vaccine.[13] Vaccination providers should consider observing all other individuals for 15 minutes after vaccination.[13]

Premedication and Prophylaxis

Antipyretics or analgesics (e.g., acetaminophen, nonsteroidal anti-inflammatory agents) may be taken for the treatment of postvaccination local or systemic symptoms, if medically appropriate.[13] However, these medications should not be used prophylactically for the purposes of prevention of post-vaccination symptoms.[13]

Dispensing and Administration Precautions

Appropriate medications and supplies for managing potential immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of COVID-19 vaccines.[1,13]

Syncope may occur following administration of parenteral vaccines, especially in adolescents.[13] Patients should be seated or lying down during vaccination.[13] Vaccination providers should consider observing vaccine recipients (especially adolescents) for 15 minutes after vaccination.[13] If syncope develops, patients should be observed until symptoms resolve.[13]

▪ Administration

COVID-19 vaccine, adjuvanted (Novavax) is administered by IM injection *only*.[1]

IM Injection

COVID-19 vaccine, adjuvanted (Novavax) (2025-2026 Formula) is supplied as a suspension in single-dose prefilled syringes.[1] Store the syringes in the original carton protected from light in a refrigerator between 2–8°C; do not freeze.[1]

The vaccine should appear as a colorless to slightly yellow, clear to mildly opalescent suspension and should not contain any visible particles.[1] Do not use if particulate matter or discoloration is observed.[1]

Each dose of Novavax COVID-19 vaccine, adjuvanted (2025-2026 Formula) contains 5 mcg of protein and 50 mcg of adjuvant.[1]

Verify that the label on the prefilled syringe states 2025-2026 Formula prior to administration.[1]

▪ Dosage

Prevention of COVID-19

For active immunization to prevent COVID-19, a single 0.5 mL dose of COVID-19 vaccine, adjuvanted (Novavax) (2025-2026 Formula) is recommended for individuals ≥12 years of age.[1] If previously vaccinated with any COVID-19 vaccine, administer the dose at least 2 months after the last dose of COVID-19 vaccine.[1]

Cautions

▪ Contraindications

Known history of severe allergic reaction (e.g., anaphylaxis) to a previous dose of Novavax COVID-19 vaccine, adjuvanted or to any component of the vaccine.[1]

▪ Warnings/Precautions

Sensitivity Reactions

Hypersensitivity Reactions.

Hypersensitivity reactions have been reported following administration of the COVID-19 vaccine, adjuvanted (Novavax).[1,10] Manifestations included urticaria, hypersensitivity, angioedema, and swelling of the face, lips, ear, and/or eyelids.[1] Within 7 days of any dose of COVID-19 vaccine, adjuvanted (Novavax), hypersensitivity reactions were reported in 30 (0.11%) participants compared to 9 (0.04%) that received placebo in clinical trials.[1] A serious reaction (generalized urticaria and facial angioedema) which lasted for 2 days was reported in one individual 2 days following receipt of the first vaccine dose.[1]

Appropriate medications and supplies to assess and manage potential immediate allergic reactions *must* be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.[1] Monitor vaccine recipients for immediate adverse reactions according to CDC guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)).[1]

Myocarditis and Pericarditis

Myocarditis and pericarditis have been reported following administration of the Novavax COVID-19 vaccine, adjuvanted in multiple clinical studies.[1,10] These events were reported in temporal relationship to vaccine administration, similar to myocarditis following mRNA COVID-19 vaccines, raising concern for a causal relationship to the Novavax COVID-19 vaccine, adjuvanted.[10] Over the course of the clinical development program for COVID-19 vaccine, adjuvanted (Novavax), 6 cases of myocarditis and pericarditis occurred after administration of the vaccine and 2 cases occurred after administration of placebo (one of whom received Novavax COVID-19 vaccine, adjuvanted 504 days prior to the event).[1,10]

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/myocarditis.html (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html)).[1]

Syncope

Syncope may occur following administration of parenteral vaccines.[1] Take appropriate measures to decrease the risk of injury if the vaccine recipient becomes dizzy or loses consciousness.[1,13] If syncope occurs, observe the patient until symptoms resolve.[13]

Altered Immunocompetence

Immunocompromised individuals, including those receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 vaccine, adjuvanted.[1] Although some individuals with altered immunocompetence (e.g., HIV infection) were included in phase 2 and 3 clinical trials evaluating the Novavax COVID-19 vaccine, the number of such individuals has been insufficient to evaluate safety of the vaccine.[9,10,20,23]

Limitations of Vaccine Effectiveness

The Novavax COVID-19 vaccine, adjuvanted may not protect all vaccine recipients against COVID-19.[1]

Specific Populations

Pregnancy.

Data are insufficient regarding the use of COVID-19 vaccine, adjuvanted (Novavax) in pregnant women to inform vaccine-associated risks during pregnancy.[1] No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in a developmental toxicity study in female rats.[1]

A pregnancy registry has been established to monitor pregnancy outcomes in women exposed to the Novavax COVID-19 vaccine, adjuvanted during pregnancy.[1] Women who are vaccinated with the Novavax COVID-19 vaccine, adjuvanted during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com/ (https://c-viper.pregistry.com/) .[1]

The US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) and the American College of Obstetricians and Gynecologists (ACOG) recommend vaccination against COVID-19 in pregnant women.[13,16] These experts state that evidence regarding the safety and efficacy of COVID-19 vaccines available from both animal and human studies indicates that the benefits of vaccination against COVID-19 during pregnancy outweigh any known or potential risks.[13]

Lactation.

Data are not available to assess whether COVID-19 vaccine, adjuvanted (Novavax) has any effects on a breast-fed infant or on milk production.[1] It is not known whether COVID-19 vaccine, adjuvanted (Novavax) is distributed into human milk.[1]

ACIP and ACOG recommend COVID-19 vaccination in all lactating patients.[13,16] ACOG states that theoretical concerns regarding the safety of vaccinating lactating women do not outweigh the potential benefits of receiving the vaccine.[16]

Females and Males of Reproductive Potential.

ACIP and ACOG recommend COVID-19 vaccination in people who are pregnant, trying to get pregnant, or might become pregnant in the future.[13,16]

COVID-19 vaccine, adjuvanted (Novavax) has not been evaluated for the potential to cause impairment of male fertility.[1]

Pediatric Use.

Safety and efficacy of COVID-19 vaccine, adjuvanted (Novavax) in adolescents 12 through 17 years of age with at least one high risk factor for severe COVID-19 outcomes is based on safety and effectiveness data in this age group and in adults.[1,20]

Safety and efficacy of COVID-19 vaccine, adjuvanted (Novavax) have not been established in patients <12 years of age; COVID-19, adjuvanted (Novavax) is not authorized for use in these individuals.[1,]

Geriatric Use.

Individuals ≥65 years of age were included in clinical trials evaluating COVID-19 vaccine (Novavax), and data from such individuals contribute to the overall assessment of safety and efficacy of the vaccine.[1,]

In a phase 3 clinical trial evaluating Novavax COVID-19 vaccine, adjuvanted (Original monovalent), 12.6% of participants were ≥65 years of age and 1.8% were ≥75 years of age.[1,] Overall, there were no notable differences in safety observed between participants ≥65 years of age and younger participants.[1,] An insufficient number of patients ≥65 years of age were included to determine if they respond differently from younger participants.[1,] From this study, among participants that received a booster dose, 15.5% were ≥65 years of age and 2.5% were ≥75 years of age.[1,] There were no notable differences in safety observed between participants ≥65 years of age and younger participants.[1,] The effectiveness of the booster dose in participants ≥65 years of age were consistent with that observed in participants aged 18—64 years.[1,]

▪ Common Adverse Effects

The most common adverse effects of COVID-19 vaccine, adjuvanted (Novavax) (>10%) reported in clinical trials in participants 12—17 years of age were injection site tenderness, injection site pain, headache, fatigue, muscle pain, malaise, nausea/vomiting, fever, and joint pain.[1,]

The most common adverse effects of COVID-19 vaccine, adjuvanted (Novavax) (>10%) reported in clinical trials in participants 18—64 years of age were injection site tenderness, injection site pain, muscle pain, fatigue, headache, malaise, joint pain, and nausea/vomiting.[1,]

The most common adverse effects of COVID-19 vaccine, adjuvanted (Novavax) (>10%) reported in clinical trials in participants ≥65 years of age were injection site tenderness, injection site pain, fatigue, muscle pain, headache, malaise, and joint pain.[1,]

The most common adverse effects of COVID-19 vaccine, adjuvanted (Novavax) (>10%) in clinical trials in participants 12—17 years of age receiving a booster dose were injection site tenderness, injection site pain, headache, muscle pain, fatigue, malaise, nausea/vomiting, joint pain, fever, and injection site redness.[1,]

The most common adverse effects of COVID-19 vaccine, adjuvanted (Novavax) (>10%) in clinical trials in participants ≥18 years of age receiving a booster dose were injection site tenderness, injection site pain, muscle pain, fatigue, headache, malaise, joint pain, and nausea/vomiting.[1,]

Drug Interactions

▪ Vaccines

There is minimal information regarding the interaction potential with COVID-19 vaccine (Novavax) and other vaccines.[1,10,24,] However, ACIP states that routine administration of all age-appropriate doses of vaccines simultaneously is recommended in children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.[13,]

Description

COVID-19 vaccine (Novavax), adjuvanted (2025-2026 Formula) is a protein subunit vaccine that contains a SARS-CoV-2 recombinant spike (rS) protein nanoparticle vaccine with Matrix-M adjuvant.[1,2,4,] Each 0.5-mL dose of the vaccine contains 5 mcg of SARS-CoV-2 recombinant spike (rS) protein from the SARS-CoV-2 Omicron variant lineage JN.1 and 50 mcg of Matrix-M adjuvant.[1,] The rS protein is produced by recombinant DNA technology using a baculovirus expression system in an insect cell line derived from the *Spodoptera frugiperda* species and the Matrix-M adjuvant is composed of saponin extracts from the soapbark tree, *Quillaja saponaria* Molina.[1,] Following administration of the Novavax COVID-19 vaccine, an immune response to the rS protein is elicited, which protects against COVID-19.[1,]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Advise the vaccine recipient or caregiver to read the FDA-approved patient labeling.[1,]

Inform the vaccine recipient or caregiver of the potential benefits and risks of vaccination with COVID-19 vaccine, adjuvanted (Novavax).[1,3,]

Instruct the vaccine recipient or caregiver to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System at 1-800-822-7967 and https://www.vaers.hhs.gov (https://www.vaers.hhs.gov) .[1,]

Inform patients of the importance of informing clinicians if they are or plan to become pregnant or plan to breast-feed.[1,3,] There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the Novavax COVID-19 vaccine during pregnancy.[1,] Women who are vaccinated with the vaccine during pregnancy are encouraged to enroll in the registry by visiting https://c-viper.pregistry.com/ (https://c-viper.pregistry.com/) .[1,3,]

Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary and herbal supplements, as well as any concomitant illnesses.[1,]

Advise patients of other precautionary information.[1,]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

COVID-19 Vaccine, Adjuvanted (Novavax) (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=COVID-19+Vaccine%2C+Adjuvanted+%28Novavax%29&collapse=1)

Parenteral

Suspension, for IM use

5 mcg of SARS-CoV-2 recombinant spike (rS) protein and 50 mcg Matrix-M adjuvant per 0.5-mL dose

Nuvaxovid® (2025-2026 Formula), Novavax (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Novavax&collapse=1)

Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%%22COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula))
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdrawn=1&investigational=1&button=) (US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula))
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula))
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)&collapse=1)
FDA Recalls, Market Withdrawals, and Safety Alerts (https://www.fda.gov/Safety/Recalls/default.htm)
HSDB (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%%22COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)%%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%%28@na+%%22COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)%%22+%%29)
New Drug Approvals (https://ahfs.ashp.org/drug-assignments.aspx)
Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)&query=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)&type=chemical) (Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-

2026%20Formula)%%5BAll+Fields%%5D) (scientific journals)
Safety-related Labeling Changes (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges) (FDA/CDER)
ToxLine (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%%22COVID-19%20Vaccine,%20Adjuvanted%20(Novavax)%20(2025-2026%20Formula)%%22) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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Contact Us

ASHP
4500 East-West Highway, Suite 900
Bethesda, Maryland 20814

Customer Service
1-866-279-0681
custserv@ashp.org (mailto:custserv@ashp.org)
softwaresupport@ashp.org (mailto:softwaresupport@ashp.org)

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