FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) 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.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration

Inspect the vial

- The Novavax COVID-19 Vaccine, Adjuvanted is a colorless to slightly yellow, clear to mildly opalescent suspension, free from visible particles.
- Gently swirl the multi-dose vial before each dose withdrawal. Do not shake.
- Parenteral drug products should be inspected visually particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer the vaccine if either of these conditions exist.

Prepare for administration

- Record the date and time of the first puncture on the vial label.
- Each multi-dose vial contains 10 doses of 0.5 mL each.
- Do not pool excess vaccine from multiple vials.
- After the first needle puncture, hold the vial between 2° to 25°C (36° to 77°F) for up to 6 hours.
- Discard vial 6 hours after the first puncture.

2.2 Administration

Administer the Novavax COVID-19 Vaccine, Adjuvanted intramuscularly.

2.3 Dosing and Schedule

Primary Series

The Novavax COVID-19 Vaccine, Adjuvanted is administered intramuscularly as a primary series of two doses (0.5 mL each) 3 weeks apart in individuals 12 years of age and older.

Booster Dose

A first booster dose (0.5 mL) of Novavax COVID-19 Vaccine, Adjuvanted may be administered intramuscularly at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate and in individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

3 DOSAGE FORMS AND STRENGTHS

The Novavax COVID-19 Vaccine, Adjuvanted is a suspension for injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 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 the 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).

5.2 Myocarditis and Pericarditis

Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted *[see Clinical Trials Experience (6.1)]*.

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).

5.3 Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.

5.5 Limitations of Vaccine Effectiveness

The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Novavax COVID-19 Vaccine, Adjuvanted. To the extent feasible, provide a copy of the VAERS form to Novavax, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and Novavax, Inc.

Adverse Reactions in Clinical Trials

Primary Series

In a clinical trial, among participants 18 through 64 years of age, solicited adverse reactions (ARs) following administration of any dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (82.2%), fatigue/malaise (62.0%), muscle pain (54.1%), headache (52.9%), joint pain (25.4%), nausea/vomiting (15.6%), injection site redness (7.0%), injection site swelling (6.3%), and fever (6.0%). In participants ≥65 years of age, solicited ARs following administration of any dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (63.4%), fatigue/malaise (39.2%), muscle pain (30.2%), headache (29.2%), joint pain (15.4%), nausea/vomiting (7.3%), injection site swelling (5.3%), injection site redness (4.8%), and fever (2.0%).

In a clinical trial, among participants 12 through 17 years of age, solicited ARs following administration of any dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (79.8%), headache (63.3%), fatigue/malaise (61.6%), muscle pain (56.9%), nausea/vomiting (23.1%), joint pain (19.5%), fever (16.7%), injection site swelling (8.5%), and injection site redness (7.7%).

Myocarditis, pericarditis, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, and decreased appetite have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted.

Booster Dose

In a clinical trial, among participants 18 years of age and older, solicited ARs following administration of a booster dose of the Novavax COVID-19 Vaccine, Adjuvanted were injection site pain/tenderness (81.1%), fatigue/malaise (63.4%), muscle pain (63.0%), headache (52.9%), joint pain (30.3%), nausea/vomiting (14.7%), injection site swelling (8.4%), injection site redness (6.3%), and fever (6.3%).

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Two-Dose Primary Series

Participants 18 years of age and older

Safety of the Novavax COVID-19 Vaccine, Adjuvanted was assessed in a clinical study conducted in the United States (US) and Mexico (NCT04611802; Study 1). In this study, 26,106 participants 18 years of age and older have received at least one dose of the Novavax COVID-19 Vaccine, Adjuvanted. Additional safety data are available from three other clinical trials in the United Kingdom (NCT04583995; Study 2), South Africa (NCT04533399; Study 3), and Australia (NCT04368988, Parts 1 and 2 in Australia and the US; Study 4) which evaluated a COVID-19 vaccine containing the SARS-CoV-2 recombinant spike (rS) protein and Matrix-M adjuvant but manufactured by a different process.

Adolescents 12 Through 17 Years of Age

Safety of the Novavax COVID-19 Vaccine, Adjuvanted in adolescents was assessed in the adolescent primary series expansion of Study 1 conducted in the US. In this study, 2,232 participants 12 through 17 years of age have received at least one dose of Novavax COVID-19 Vaccine, Adjuvanted (n=1,487) or placebo (n=745).

Safety Data from Study 1

In Study 1, an ongoing Phase 3, multicenter, randomized, observer-blinded, placebo-controlled study, participants 18 years of age and older have received the Novavax COVID-19 Vaccine, Adjuvanted (n=19,735) or placebo (n= 9,847). Overall, 52.0% were male, 48.0% were female; 75.0% were White, 11.8% were Black or African American, 4.1% were Asian, 6.7% were American Indian (including Native Americans) or Alaskan Native, and 1.6% were multiple races; 21.9% were Hispanic/Latino. Demographic characteristics of participants were well balanced between the Novavax COVID-19 Vaccine, Adjuvanted and placebo groups. During the study, COVID-19 vaccines authorized for emergency use became available, and participants, when

Storage of Unpunctured Vial

Store the unpunctured multi-dose vaccine vial in a refrigerator between 2° to 8°C (36° to 46°F).

Do not freeze.

Protect from light.

Storage After First Needle Puncture of the Vial

After first puncture, hold the vial between 2°to 25°C (36°to 77°F) for up to 6 hours. Discard the vial 6 hours after the first puncture.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at:
https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, visit the website or call the telephone number provided below.

Website	Telephone number
www.NovavaxCovidVaccine.com	1-844-NOVAVAX (1-844-668-2829)

This Full EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please see www.NovavaxCovidVaccine.com.

Manufactured for:
Novavax, Inc., Gaithersburg, MD, 20878