
COVID-19 Vaccine Information Brief

October 9, 2023

IMPORTANT/NEW COVID-19 Vaccine Information

- Novavax COVID-19 Vaccine, Adjuvanted Authorized
- 2023–24 COVID-19 Vaccine Up to Date Definition
- Simultaneous Administration of COVID-19 and Other Vaccines
- Remove ALL Bivalent Moderna and Pfizer COVID-19 Vaccines and Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) from IRIS and Physical Inventory

Novavax COVID-19 Vaccine, Adjuvanted Authorized

On October 3, 2023, the Food and Drug Administration [amended the emergency use authorization](#) (EUA) of Novavax COVID-19 Vaccine, Adjuvanted to include the 2023-2024 formula. The Novavax COVID-19 Vaccine, Adjuvanted, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5 (2023-2024 formula). CDC is currently in the process of updating the Interim Clinical Considerations guidance. **The Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized for use in the United States.**

The Iowa Immunization Program will notify providers when Novavax is available to order through the VFC and BAP Programs.

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is authorized for use in individuals 12 years of age and older as follows:

- **Individuals previously vaccinated with any COVID-19 vaccine:** one dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is administered at least 2 months after receipt of the last previous dose of an original monovalent (Original) or bivalent (Original and Omicron BA.4/BA.5) COVID-19 vaccine.
- **Individuals not previously vaccinated with any COVID-19 vaccine:** two doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-24 Formula) are administered three weeks apart.

- **Immunocompromised individuals:** an additional dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula). Additional doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) 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.

Vaccine Storage and Handling

- Store unpunctured multi-dose vials in the refrigerator between 2 to 8°C (36 to 46°F).
- Do not freeze. After the first needle 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.
- The vials have a royal **blue** cap.

COVID-19 Vaccine Resources

- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
 - [Fact Sheet for Recipients and Caregivers](#)
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2023–24 COVID-19 Vaccine Up to Date Definition

- Everyone aged 5 years and older are recommended to get one 2023–24 COVID-19 vaccine to be up to date.
 - **Children aged 6 months – 4 years** and **people who are moderately or severely immunocompromised** need multiple doses, including at least one 2023–24 COVID-19 vaccine dose to be up to date.
 - People who are moderately to severely immunocompromised may get additional doses of the 2023–24 COVID-19 vaccine.
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Simultaneous Administration of COVID-19 and Other Vaccines

- In accordance with [General Best Practice Guidelines for Immunization](#), routine administration of all age-appropriate doses of vaccines simultaneously (i.e., administering more than one vaccine on the same clinic day or “coadministration”) is recommended for children, adolescents, and adults if there are no contraindications at the time of the healthcare visit.

- Providers may simultaneously administer COVID-19, influenza, and respiratory syncytial virus (RSV) vaccines to eligible patients; the [Health Alert Network \(HAN\)](#) published on September 5, 2023 may be consulted for additional information about simultaneous administration of these vaccines
 - Simultaneous administration of COVID-19 vaccine and nirsevimab (a long-acting monoclonal antibody for certain infants and young children for prevention of RSV) is recommended
 - Coadministration of COVID-19 and RSV vaccine for older adults is acceptable
 - There are additional considerations of administering an orthopoxvirus vaccine and COVID-19 vaccine
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Remove ALL Bivalent Moderna and Pfizer COVID-19 Vaccines and Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) From IRIS and Physical Inventory

As part of FDA's actions, the bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States. Additionally, Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized for use in the United States.

To minimize the risk of vaccine administration errors, providers should:

- Remove all bivalent mRNA COVID-19 vaccines from storage units immediately, even if the vaccines are not expired.
- Removal all Novavax Vaccine, Adjuvanted (Original monovalent) from storage units immediately, even if the vaccines are not expired.
- Vaccines should be removed from IRIS using the reason code "Open vial but all doses not administered".
 - Healthcare providers can use the [Adjusting COVID-19 Vaccine Inventory for Wastage](#) instructions to account for wasted doses.
- **Moderna and Pfizer bivalent mRNA and Novavax (Original monovalent) COVID-19 vaccines should be disposed of at the provider level.** The federal government does not have a method to return wasted or expired COVID-19 vaccines.
- IRIS staff are available to help manage IRIS inventory by calling 800-374-3958.

KEY ACTIONS ITEM:

- Remove all bivalent mRNA COVID-19 vaccines from storage units immediately, **even if the vaccines are not expired.**

- Removal all Novavax Vaccine, Adjuvanted (Original monovalent) from storage units immediately, **even if the vaccines are not expired.**
 - Dispose of bivalent mRNA and Novavax (original monovalent) COVID-19 vaccines at the provider level.
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