# 2024-2025 Pfizer-BioNTech COVID-19 Vaccine for Age 5 to 11 Years

vaccine protocol for children Age 5 to 11 Years

**Document reviewed and updated: August 28, 2024**

## Condition for protocol

To reduce incidence of morbidity and mortality of COVID-19 disease.

## Policy of protocol

The nurse will implement this protocol for COVID-19 vaccination using the 2024-2025 Pfizer-BioNTech COVID-19 vaccine product for 5 through 11 years of age.

## Condition-specific criteria and prescribed actions

**Delete this entire paragraph before printing/signing protocol.**

[Instructions for persons adopting these protocols: The table below lists indication, contraindication, and precaution criteria and suggested prescribed actions that are necessary to implement the vaccine protocol. The prescribed actions include examples shown in brackets but may not suit your institution’s clinical situation and may not include all possible actions. A licensed prescriber must review the criteria and actions and determine the appropriate prescribing action.]

Indications

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Person is currently healthy and age 5 through 11 years. | Proceed to vaccinate if meets remaining criteria. |
| Child is under 5 years of age. | Do not vaccinate with this product.  Follow the protocol for the *2024-2025 Pfizer-BioNTech COVID-19 Vaccine for 6 Months to 4 Years.* |
| Child has not received any previous COVID-19 vaccine. | Proceed to vaccinate. |
| Child received previous COVID-19 vaccine(s). | Proceed to vaccinate. |
| Person is 12 years or older. | Do not vaccinate with this product. Refer to the protocol for  *2024-2025 Pfizer-BioNTech COVID-19 Vaccine for Age 12 Years and Older.* |
| Child is currently healthy but has a chronic medical condition. | Proceed to vaccinate. |
| Child with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies. | Proceed to vaccinate. Counsel the individual and/or parent/guardian about:  1) The potential for reduced immune responses.  2) The need to continue to follow [current guidance](https://www.cdc.gov/coronavirus/2019-ncov/index.html) to protect themselves. |
| Child who falls into one of following categories of moderate to severe immunocompromise:   * Active treatment for solid tumor and hematologic malignancies. * Receipt of solid-organ transplant and taking immunosuppressive therapy. * Receipt of CAR-T-cell or hematopoietic stem cell transplant (within two years of transplantation or taking immunosuppression therapy). * Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome). * Advanced or untreated HIV infection. * Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day), alkylating agents, antimetabolites, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory. | Proceed to vaccinate using schedule for children with immunocompromising conditions.  [Refer to primary care provider if additional doses may be indicated] |

Contraindications

|  |  |
| --- | --- |
| Criteria: Allergies | Prescribed action |
| Person had a severe allergic reaction (e.g., anaphylaxis) to a previous dose of mRNA COVID-19 vaccine or any of its components. | Do not vaccinate. |

Precautions

|  |  |
| --- | --- |
| Criteria | Prescribed action |
| Child has a moderate to severe illness defined as temperature \_\_\_\_°F/°C or higher with symptoms such as: {to be determined by medical prescriber} | Defer vaccination and {to be determined by medical prescriber} |
| Person had a non-severe immediate (within 4 hours) allergic reaction to a previous dose of COVID-19 vaccine or a reaction of any severity to a product that contains polysorbates. | The person may be vaccinated but should seek counsel from an allergist-immunologist to discuss risks and benefits of vaccination.  Persons who choose vaccination should be observed for 30 minutes in a vaccination site that has equipment and personnel that is familiar with managing anaphylaxis. |
| Person has a history of Multisystem Inflammatory Syndrome in Children (MIS-C). | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| Person has a history of myocarditis or pericarditis after a previous dose of mRNA vaccine. | Refer to their primary care provider to receive an assessment of their current health condition and assessment of individual benefits and risks. |
| History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous).  *This precaution does not include allergies not related to vaccines or injectable therapies (e.g., food, pet, environmental, or latex allergies; oral medications – including the oral equivalents of injectable medications).* | May be vaccinated.  Provide counseling on the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of COVID-19 vaccination.  Observe them for 30 minutes after vaccination. |
| Person had a delayed local allergic reaction (e.g., erythema, induration, pruritis at the injection site). | Proceed to vaccinate. Give vaccine in the opposite arm from where the first dose was given. |
| Person has received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment in the past 90 days. | Proceed to vaccinate when recovered from acute illness and isolation period is complete. |
| Person received monoclonal antibodies or convalescent plasma as post-exposure prophylaxis. | Proceed to vaccinate when quarantine period is complete. |

## Prescription

### Primary vaccination:

Give 2024-2025 Pfizer-BioNTech COVID-19 Vaccine for 5 through 11 years (vials with blue caps and labels with blue borders); 10 micrograms, **0.3 mL**, intramuscular (IM):

* One 2024-2025 vaccine dose for those who were never vaccinated.
* Give one dose 2024-2025 vaccine at least 2 months following any previous COVID-19 vaccine dose.

### For persons with immunocompromising conditions:

Give 2024-2025 Pfizer-BioNTech COVID-19 Vaccine for 5 through 11 years (vials with blue caps and labels with blue borders); 10 micrograms, 0.2 mL, intramuscular (IM), 3 dose series for those who have not been vaccinated:

* Give the second dose 3 weeks following the first dose.
* Give the third dose at least 4 weeks following the second dose.
* If started series with previous COVID-19 vaccine, complete series with 2024-2025 vaccine at the recommended intervals.

May give one or more additional 2024-2025 vaccine doses at least 2 months following the last dose based on clinical condition.

## Medical emergency or anaphylaxis

Follow pre-established agency protocol for anaphylaxis.

## Question or concerns

**Insert overseeing medical consultant’s information below and delete this sentence before printing/signing.**

In the event of questions or concerns call (insert name) at (insert phone number).

**This protocol shall remain in effect until rescinded.**

Name of prescriber (please print):

Prescriber signature:

Date:

## Ingredient listing for 2024-2025 Pfizer-BioNTech COVID-19 vaccine for age 5 through 11 years (single dose vials with blue caps and labels with blue borders)

Each 0.3 mL dose is formulated to contain 10 mcg of a modRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant lineage KP.2.

Each 0.3 mL dose also includes the following ingredients:

* Lipids (0.14 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.02 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, 0.06 mg cholesterol.
* 31 mg sucrose.
* 0.06 mg tromethamine.
* 0.4 mg tromethamine hydrochloride.

**More information**:

* The 2024-2025 Pfizer-BioNTech COVID-19 vaccine does not contain preservative.
* The vial stoppers are not made with natural rubber latex.

Taken from the *FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION PFIZER-BIONTECH COVID-19 VACCINE* [FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE: EMERGENCY USE AUTHORIZATION OF PFIZER-BIONTECH COVID-19 VACCINE (2024−2025 FORMULA), FOR 6 MONTHS THROUGH 11 YEARS OF AGE (www.fda.gov/media/167211/download?attachment)](https://www.fda.gov/media/167211/download?attachment).