Pfizer-BioNTech COVID-19 Vaccines
Vaccine Preparation and Administration Summary

General information

Composition	Age Indications	Cap/label border	Diluent	Use For	Dosage
Monovalent	6 months through 4 years	Maroon capped vial/Maroon-bordered label	2.2 mL	Primary 1st and 2nd doses	3 μg/0.2 mL
Bivalent	6 months through 4 years	Maroon capped vial/Maroon-bordered label	2.2 mL	Primary 3rd dose	3 μg/0.2 mL
Monovalent	5 through 11 years	Orange capped vial/Orange-bordered label	1.3 mL	Primary series doses	10 μg/0.2 mL
Bivalent	5 through 11 years	Orange capped vial/Orange-bordered label	1.3 mL	Booster doses	10 μg/0.2 mL
Monovalent	12 years and older	Gray capped vial/Gray-bordered label	NONE	Primary series doses	30 μg/0.3 mL
Bivalent Single-dose Vials and Multidose Vials	12 years and older	Gray capped vial/Gray-bordered label	NONE	Booster doses	30 μg/0.3 mL

Schedule

Use the Interim Schedule for Persons 6 Months of Age and Older to determine if a doses is needed or to schedule doses.

Preparation and Administration

Remove vaccine from the storage unit.

- If the vaccine is frozen, allow to thaw before preparing the injection. Thaw vaccine in the refrigerator or at room temperature. Unpunctured vials may be stored:
  - In the refrigerator for up to 10 weeks OR
  - At room temperature between 8°C and 25°C (46°F and 77°F) for a total of 12 hours
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated temperatures.
- Choose the correct vaccine product based on the age of the recipient and the dose – primary versus booster. Check the vaccine for age indications and composition of the vaccine (monovalent; bivalent)

Primary & Booster series dose

Ages: 6 months through 4 years
(Maroon capped vial and bordered label)

MONOVALENT Primary Series
(Dose 1 & 2)

BIVALENT Primary Series
(Dose 3)

Ages: 5 through 11 years
(Orange capped vial and bordered label)

MONOVALENT Primary Series

BIVALENT Booster Dose

Ages: 12 and older
(Gray capped vial and bordered label)

MONOVALENT Primary Series

BIVALENT Booster Dose
Single-dose and Multidose Vials

Check the vial label to ensure the expiration date or beyond-use date/time has not passed.

- Use Pfizer expiration date tool at https://lotexpiry.cvdvaccine.com
- Check beyond-use date/times
  - Unpunctured vials may be stored between 2°C and 8°C (36°F-46°F) for up to 10 weeks
  - Unpunctured vials may be stored between 8°C and 25°C (46°F and 77°F) for a total of 12 hours
  - Once mixed, punctured vials can be stored between 2°C to 25°C (35°F to 77°F) for up to 12 hours
- **NOTE:** The beyond-use date/time replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use date/time has passed.

Follow aseptic technique

- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled. Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.
- Use a new, sterile needle and syringe for each injection
- Single-dose vials: Withdraw ONE dose for ONE injection. Discard vial and any remaining vaccine after 1 dose.

Mix vaccine with 0.9% sodium chloride, preservative-free diluent if indicated.

- Use a new vial of diluent for each vial.

Diluent	Maroon capped vial 6 months through 4 years		Orange capped vial 5 through 11 years		Gray capped vial 12 years and older	
0.9% sodium chloride; preservative free diluent	Monovalent	Bivalent	Monovalent	Bivalent	Monovalent	Bivalent SDV and MDV
	2.2 mL	2.2mL	1.3 mL	1.3 mL	NONE	NONE

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Gently invert the thawed vaccine vial 10 times. Do not shake the vial.

- The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.

COVID-19 vaccine is administered by intramuscular injection.

Choose the correct equipment.

- Needle gauge: 22-25 gauge
- Needle length varies by recipient's age, gender, weight, and injection site. See chart: Vaccine Administration: Needle Gauge and Length (cdc.gov)

Withdraw the correct dosage.

- Primary series and booster dosages (injection volume) are the same
- Single-dose vials should be used for only **ONE** recipient for **ONE** injection.
- If the amount of vaccine remaining in the vial (multidose or single-dose vials) cannot provide a full dose, discard the vial and any excess volume. Do NOT combine from 2 or more vials to obtain a dose

Ages 6 months through 4 years: 0.2 mL/3 *µg*

Ages 5 through 11 years: 0.2 mL/10 *µg*

Ages 12 years and older 0.3 mL/30 *µg*

Administer vaccine by intramuscular (IM) injection

Ages	Injection site
6 months through 2 years	Vastus lateralis muscle in the anterolateral thigh .
3 years and older	Deltoid muscle in the upper arm. Alternatively, the anterolateral thigh can be used.

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes for persons with:**
  - An allergy-related contraindication to a different type of COVID-19 vaccine
  - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
  - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
- **15 minutes:** All other persons

Document the vaccination

Document each recipient's vaccine administration information in the:

- Medical record:
  - Vaccine and the date administered, manufacturer, lot number, vaccination site and route
  - Name and title of the person administering the vaccine
- Recipient's vaccination record card:
  - Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Indicate if the vaccine dose is a monovalent or bivalent product, if possible.
  - Report the vaccination to the appropriate state/local immunization information system (IIS)

Contraindications and precautions

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered. Use CDC's COVID-19 Prevaccination Screening Checklist and Guidance to determine if the vaccine may be administered.

Contraindications

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the COVID-19 vaccine

Precautions

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

Report adverse reactions and administration errors

Healthcare professionals are required to report to the Vaccine Adverse Event Reporting System (VAERS) including:

- Vaccine administration errors (whether associated with an adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccination)
- Multisystem inflammatory syndrome (MIS) in adults and children
- Cases of myocarditis and pericarditis (for mRNA vaccines)
- Cases of COVID-19 that result in hospitalization or death
- Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA

Healthcare professionals are encouraged to report to VAERS clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event.