General information

<table>
<thead>
<tr>
<th>Composition</th>
<th>Age Indications</th>
<th>Cap/label border</th>
<th>Diluent</th>
<th>Use For</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monovalent</td>
<td>6 months through 4 years</td>
<td>Maroon vial cap Maroon-bordered label</td>
<td>2.2 mL</td>
<td>Primary series doses</td>
<td>3 µg/0.2 mL</td>
</tr>
<tr>
<td>Monovalent</td>
<td>5 through 11 years</td>
<td>Orange vial cap Orange-bordered label</td>
<td>1.3 mL</td>
<td>Primary series doses</td>
<td>10 µg/0.2 mL</td>
</tr>
<tr>
<td>Bivalent</td>
<td>5 through 11 years</td>
<td>Orange vial cap Orange-bordered label</td>
<td>1.3 mL</td>
<td>Booster doses</td>
<td>10 µg/0.2 mL</td>
</tr>
<tr>
<td>Monovalent</td>
<td>12 years and older</td>
<td>Gray vial cap Gray-bordered label</td>
<td>NONE</td>
<td>Primary series doses</td>
<td>30 µg/0.3 mL</td>
</tr>
<tr>
<td>Bivalent</td>
<td>12 years and older</td>
<td>Gray vial cap Gray-bordered label</td>
<td>NONE</td>
<td>Booster doses</td>
<td>30 µg/0.3 mL</td>
</tr>
</tbody>
</table>

Schedule

Use the Interim Schedule for Persons 6 Months of Age and Older to determine if a dose is needed or 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 series dose

- Use MONOVALENT vaccine (Maroon capped vial and bordered label)
  - Ages: 6 months through 4 years

Booster dose

- Booster dose is NOT authorized for ages 6 months through 4 years
- Use BIVALENT vaccine (Orange capped vial and bordered label)
  - Ages: 5 through 11 years

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

Mix vaccine with 0.9% sodium chloride; preservative-free diluent if indicated.
- Use a new vial of diluent for each vial.

<table>
<thead>
<tr>
<th>Diluent</th>
<th>Maroon capped vial 6 months – 4 years</th>
<th>Orange capped vial 5 through 11 years</th>
<th>Gray capped vial 12 years and older</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.9% sodium chloride; preservative free diluent</td>
<td>Monovalent</td>
<td>Monovalent</td>
<td>Bivalent</td>
</tr>
<tr>
<td>2.2 mL</td>
<td>1.3 mL</td>
<td>1.3 mL</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>SDV and MDV</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Ages</th>
<th>dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months through 4</td>
<td>0.2 mL/3 µg</td>
</tr>
<tr>
<td>5 through 11 years</td>
<td>0.2 mL/10 µg</td>
</tr>
<tr>
<td>12 years and older</td>
<td>0.3 mL/30 µg</td>
</tr>
</tbody>
</table>

Administer vaccine by intramuscular (IM) injection

<table>
<thead>
<tr>
<th>Ages</th>
<th>Injection site</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months through 2</td>
<td>Vastus lateralis muscle in the anterolateral thigh</td>
</tr>
<tr>
<td>3 years and older</td>
<td>Deltoid muscle in the upper arm. Alternatively, the anterolateral thigh can be used.</td>
</tr>
</tbody>
</table>

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.