

Health care provider (HCP) Guide

For COVID-19 mRNA Vaccine BNT162b2 (Pfizer- BioNTech)

HCP Guide for Pediatrics 5 to 11 years of Age

The objective of the Health Provider guide is to provide essential information such as administration, preparation, warnings, contraindications, AEs, reactions, other instructions to HCPs prior to administration, other reporting requirements to ensure the safe and effective use of the product and appropriate management of the important risk. It is advised to be read carefully before giving the vaccine.

This document is approved by The Executive Directorate of Pharmacovigilance at SFDA.

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Description of COVID-19:

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus, SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus.

What does COVID-19 mRNA vaccine for?

COVID-19 mRNA Vaccine is a vaccine used for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.

The modRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the RNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

Posology and method of administration:

Dosing and schedule

Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide active immunization to prevent COVID-19 in individuals 5 through 11 years of age. It is approved for use as a 2-doses primary series for the prevention of COVID-19 in individuals 5 through 11 years of age.

Pfizer-BioNTech COVID-19 Vaccine is supplied in multiple dose vials with orange caps and labels with orange borders for use in individuals 5 through 11 years of age is based on safety and effectiveness data in this age group and in adolescents and adults.

Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 5 years of age.

For adolescents 12 through 17 years of age, a different formulation and a different presentation of this formulation of the Pfizer-BioNTech COVID-19 Vaccine are authorized.

Method of administration:

Primary Series:



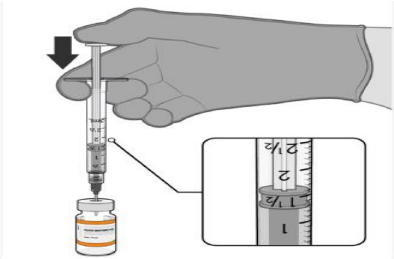
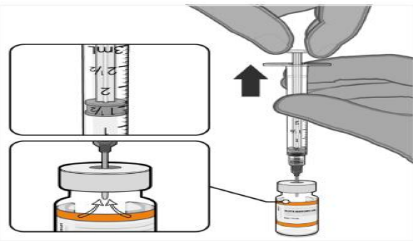
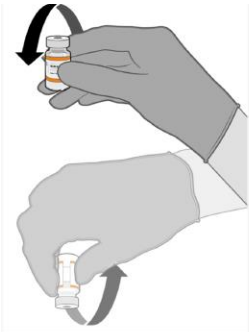
- The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of 2 doses (0.2 mL each) 3 weeks apart in individuals 5 through 11 years of age.
- The vaccine will be a white to off-white suspension.
- After dilution, vials of Pfizer-BioNTech COVID-19 contain 10 doses of 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and contents


Observation time after vaccine administration:

Vaccine recipients should be monitored for **15 minutes** after vaccination, with a longer observation period when indicated after clinical assessment.

Preparation:

- The multi-dose vial is stored frozen and must be thawed prior to dilution.
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)] (see Storage and Handling).
- Prior to dilution, the thawed suspension may contain white to off-white liquid suspension and may contain opaque amorphous particles.
- Before dilution, mix by inverting vaccine vial gently 10 times, do not shake.
- Do not use if liquid is discolored or if other particles are observed.
- Dilute the vial contents using 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP (not provided) to form the Pfizer-BioNTech COVID-19 Vaccine. ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.3 mL of diluent after dilution, 1 vial contains 10 doses of 0.2 mL.
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.
- Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.
- After dilution, the vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discoloration is observed. If particulates or discoloration are observed, discard the vial.
- Strictly adhere to aseptic technique. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.

	<p>Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states “Age 5y to < 12y.”</p>
	<p>Before dilution, mix by inverting vaccine vial gently 10 times. Do not shake.</p>
	<p>Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.</p>
	<p>Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.</p>
	<p>The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter. Gently invert the vial and Do not shake.</p>

	<p>Record the date and time of first vial puncture on the vial label.</p> <p>Store between 2°C to 25°C (35°F to 77°F).</p> <p>Discard any unused vaccine 12 hours after dilution.</p>
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Special warnings, precautions and contraindications:

Contraindications

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.

See Full (Summary of product characteristics of vaccines).

Special warnings and precautions for use

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions.

Myocarditis and Pericarditis

Increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

Syncope

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

Altered Immunocompetence

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

Interaction with other medicinal products and other forms of interaction

There are no data to assess the concomitant administration of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

Adverse reactions

Adverse reactions following administration of any primary series dose included:

General disorder:

Injection site pain, fatigue, chills, pyrexia, injection site swelling, Injection site redness, Malaise and injection site pruritus.

Blood and lymphatic system disorder:

Lymphadenopathy.

Immune System Disorders:

severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema)

Nervous system disorders:

Headache, dizziness, hypoesthesia acute peripheral facial paralysis.

Gastrointestinal disorder common:

Nausea, vomiting, diarrhea.

Cardiovascular disorder:

Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine outside of clinical trials.

Storage and handling

Vial Storage Prior to Use

- Cartons of Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may arrive frozen at ultra-cold conditions in thermal containers with dry ice or at -25°C to -15°C (-13°F to 5°F).
- Once received, frozen vials may be immediately transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. A carton of 10 vials may take up to 4 hours to thaw at this temperature.

Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F). Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed they should not be refrozen.

Vial Storage During Use

Before dilution:

- If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.
- Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with orange caps and labels with orange borders may be stored at 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to dilution.

After dilution:

- the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution.

- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)].

Transportation of Vials

- If local redistribution is needed, undiluted vials may be transported at -90°C to -60°C (-130°F to -76°F) or at 2°C to 8°C (35°F to 46°F).

Special precautions for storage

- Store in a freezer at -90 °C to -60 °C.
- Store in the original package in order to protect from light.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- Do not refreeze thawed vials.

Information to be provided to vaccine recipients/caregivers parents:

- As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the PIL for Recipients and Caregivers.
- Provide a copy of guide for Children’s parents vaccinated with Pfizer-BioNTech COVID-19 prior to the individual receiving Pfizer- BioNTech COVID-19 Vaccine. Highlight the importance of second dose schedule.

Refer to SPC for further information.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance Center (NPC):

Saudi Food and Drug Authority (SFDA)

The National Pharmacovigilance Centre (NPC)

SFDA call center: [19999](tel:19999)

E-mail: npc.drug@sfd.gov.sa

Website: <http://ade.sfd.gov.sa/>

Pharmacovigilance department in Pfizer Mobile: +966 53 906-9565

E-mail: SAU.AEReporting@pfizer.com

Tel: +966 12 229-3633