BOOSTER DOSE FOR 12 YEARS OF AGE AND OLDER
DO NOT DILUTE

Health care provider (HCP) Guide

PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5) BOOSTER DOSE FOR 12 YEARS OF AGE AND OLDER DO NOT DILUTE

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 read it carefully before giving the vaccine.
This document is approved by The Executive Directorate of Pharmacovigilance at SFDA.

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 is PFIZER-BIONTECH COVID-19 VACCINE, BIVALENT (ORIGINAL AND OMICRON BA.4/BA.5??

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) for active immunization to prevent COVID-19 in individuals 12 years of age and older. Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent. It is supplied in single dose and multiple dose vials with gray caps and labels with gray borders.

Posology and method of administration:

DOSAGE AND ADMINISTRATION
The storage, preparation, and administration information in this HCP guide apply to the Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in:
• single dose vials with gray caps and labels with gray borders, and
• multiple dose vials with gray caps and labels with gray borders.

DO NOT DILUTE PRIOR TO USE.

Booster dose :
Pfizer-BioNTech COVID-19 Vaccine, Bivalent is administered as a single booster dose at least 2 months after:

- completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine; or
- receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine

The vaccine may not protect everyone.

Revised and approved By Saudi Food & Drug authority, October 2022.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent which is supplied in a single dose and multiple dose vial with a **gray cap** and a **label with a gray border**, should NOT be used in individuals 5 through 11 years of age.

Storage and Handling
During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
Do not refreeze thawed vials.
Vial Storage Prior to Use
Cartons of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may arrive frozen at ultra-cold conditions in thermal containers with dry ice.
Once received, frozen vials may be immediately transferred to the refrigerator [2ºC to 8ºC (35ºF to 46ºF)], 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 single dose vials may take up to 2 hours to thaw at this temperature. A carton of 10 multiple dose vials may take up to 6 hours to thaw at this temperature.
Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90ºC to -60ºC (-130ºF to -76ºF) for up to 12 months from the date of manufacture.
Do not store vials at -25°C to -15°C (-13°F to 5°F). Once vials are thawed, they should not be refrozen. If cartons of Pfizer-BioNTech COVID-19 Vaccine, Bivalent are received at 2°C to 8°C (35ºF to 46ºF), they should be stored at 2°C to 8°C (35ºF to 46ºF). Check that the carton has been updated to reflect the 10-week refrigerated expiry date.
Regardless of storage condition, the vaccine should not be used after 12 months from the date of manufacture printed on the vial and cartons.
Vial Storage During Use
If not previously thawed at 2ºC to 8ºC (35ºF to 46ºF), allow vials to thaw at room temperature [up to 25ºC (77ºF)] for 30 minutes.
Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to the first puncture. After first puncture, the multiple dose vial should be held between 2ºC to 25°C (35°F to 77°F). Multiple dose vials should be discarded 12 hours after first puncture.
Transportation of Vials
If local redistribution is needed, 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).
Dose Preparation

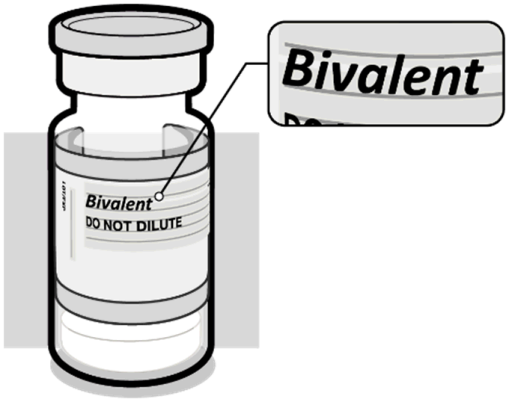
- Pfizer-BioNTech COVID-19 Vaccine, Bivalent vials contain a frozen suspension without preservative. Each vial must be thawed prior to administration.

DO NOT DILUTE prior to use.

- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)].
- Refer to thawing and preparation instructions in the panels below.

Preparation Instructions

Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial with Gray Cap and Label with Gray Border –VIAL VERIFICATION



Gray cap and label with gray border.

- Verify that the vial of Pfizer-BioNTech COVID-19
- Vaccine, Bivalent:
  - has a gray cap and a label with a gray border
  - states Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).

THAWING PRIOR TO USE

Store in the refrigerator for up to 10 weeks prior to use.

- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)].
    - A carton of 10 single dose vials may take up to 2 hours to thaw.
    - A carton of 10 multiple dose vials may take up to 6 hours to thaw.
  - Allowing vial(s) to sit at room mtemperature [up to 25ºC (77ºF)] for 30 minutes.
- Thawed vials can be stored in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 10 weeks prior to use.
- Thawed vials may be stored at room temperature [up to 25ºC (77ºF)] for up to 12 hours prior to use.

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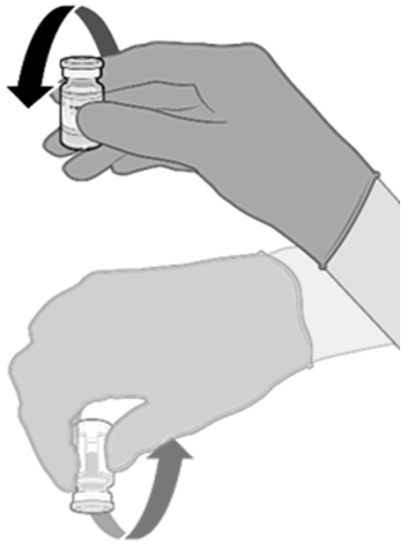
<td> 
Gently × 10</td>
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Before use, mix by inverting vaccine vial gently 10 times.
Do not shake.
Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
Do not use if liquid is discolored or if particles are observed after mixing.

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<tr>
<td colspan="2">PREPARATION OF INDIVIDUAL 0.3 mL DOSES</td>
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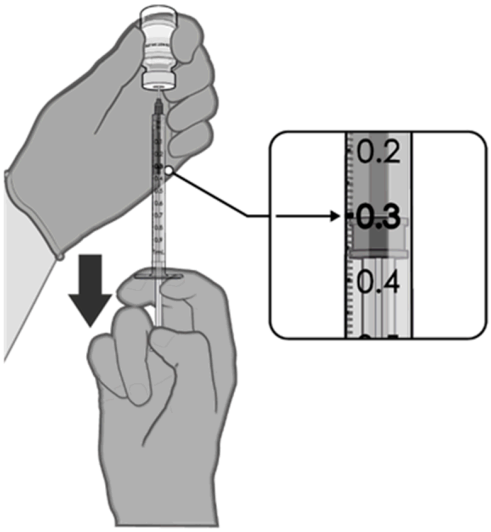
<td> 

Withdraw 0.3 mL dose of vaccine.</td>
<td>Single Dose Vial

Withdraw a single 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
Administer immediately.
Discard vial and any excess volume.

Multiple Dose Vial

Multiple dose vials contain 6 doses of 0.3 mL each.
Withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent preferentially using low dead-volume syringes and/or needles. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.
Administer immediately.
If the amount of vaccine remaining in a multiple dose vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.

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<tr>
<td colspan="2">Multiple Dose Vial – Record Date and Time of First Puncture</td>
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 **Record the date and time of** 12 hours after **first puncture.** **Use within 12 hours after first puncture.**	• Record the date and time of first vial puncture on the Pfizer-BioNTech COVID-19 • Vaccine, Bivalent multiple dose vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 12 hours after first puncture.

Administration
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The vaccine will be a white to off-white suspension. Do not administer if vaccine is discolored or contains particulate matter. After withdrawing a single 0.3 mL dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent, administer immediately.

Adverse Reactions
Adverse reactions following administration of a booster dose of the Pfizer-BioNTech COVID-19 Vaccine or the bivalent vaccine (Original and Omicron BA.1) that have been reported in clinical trials include injection site pain, fatigue, headache, muscle pain, chills, joint pain, injection site swelling, fever, injection site redness, lymphadenopathy, nausea, malaise, pain in extremity, rash, and decreased appetite (Please refer to summary of product characteristic (SPC) for more information).

Adverse Reactions Identified in Post Authorization Experience
Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (e.g., rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
Myocarditis and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.
Additional adverse reactions, some of which may be serious, may become apparent with post-authorization use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Observation time after vaccine administration:
There is a remote chance that these vaccines could cause a severe allergic reaction. A severe allergic reaction would usually occur within a **few minutes to 1 hour** after getting a dose. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination.

Special warnings, precautions and contraindications:

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

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent supplied in single doseand multipledose vials also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethyleneglycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2- distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

Special Warnings and precautions for use:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.

Myocarditis and Pericarditis:
Post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.
Post marketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination.
For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and 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. The CDC has published
considerations related to myocarditis and pericarditis after vaccination.

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, Bivalent.
Limitation of Effectiveness
Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Special population:

For individuals 5 through 11 years of age, a different presentation and formulation of the Pfizer-BioNTech.
Pfizer-BioNTech COVID-19 Vaccine Bivalent does not include use in individuals younger than 5 years of age.

Geriatric:

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine Bivalent include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.

Pregnancy and Breast-feeding:

- There is currently no scientific evidence that the vaccine is safe for pregnant or breastfeeding women However, the vaccine should not be withheld from pregnant and breastfeeding women with high risk.
- Administration of the vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.
- Health care providers should review the available data on risks and benefits of vaccination with pregnant patients, including the risks of not getting vaccinated in the context of the individual patient's current health status, and risk of exposure, including the possibility for exposure at work or home.
- Health care providers are encouraged to be up to date with the new safety recommendation about COVID-19 vaccines.

Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine or the Pfizer BioNTech COVID-19 Vaccine, Bivalent on the breastfed infant or on milk production/ excretion.

Interaction:

Concomitant administration of COVID-19 mRNA Vaccine, Bivalent with other vaccines has not been studied. Do not mix COVID-19 mRNA Vaccine, Bivalent with other vaccines/products in the same syringe.

Vaccine Presentation:

1.Single Dose Vials: Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection. Single dose vials with gray caps and labels with gray borders are supplied in a carton containing 10 single dose vials. One vial contains 1 dose of 0.3 mL.

- Carton of 10 single dose vials: NDC 59267-1404-2
- Single dose vial: NDC 59267-1404-1

2.Multiple Dose Vials: Pfizer-BioNTech COVID-19 Vaccine, Bivalent is a suspension for intramuscular injection. Multiple dose vials with gray caps and labels with gray borders are supplied in a carton containing 10 multiple dose vials. One vial contains 6 doses of 0.3 ml.

- Carton of 10 multiple dose vials: NDC 59267-0304-2
- Multiple dose vial: NDC 59267-0304-1

Information to be provided to vaccine recipients/caregivers:

- 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 vaccine recipient guide prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine, Bivalent.
- Highlight the importance of second dose schedule and the booster doses.

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).

*There is an additional HCP Guide for individuals (from 5 to 11 years of age) and the formulation is different and should not be used in individuals from 12 years of age and older.

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

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

Website: http://ade.sfda.gov.sa/

Pharmacovigilance department in Pfizer Mobile: +966 53 906-9565
E-mail : SAU.AEReporting@pfizer.com

Tel: +966 12 229-3633