FOR 12 YEARS OF AGE AND OLDER

Health care provider (HCP) Guide

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

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 COVID-19 mRNA is?

COVID-19 mRNA Vaccine BNT162b2 is a vaccine used for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals 12 years of age and older.
The mRNA in the Pfizer-BioNTech COVID-19 Vaccine is formulated in lipid nanoparticles, 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.
Pfizer-BioNTech COVID-19 Vaccine is used in individuals 5 years of age and older and this guide is for individuals 12 years of age and older.

Posology and method of administration:

Primary Series : The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a primary series of two doses (0.3 mL each) three weeks apart in individuals 12 years of age and older.

A third dose of the Pfizer-BioNTech COVID-19 vaccine (0.3 mL) at least 28 days following the second dose is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Booster dose :

A single Pfizer-BioNTech COVID-19 Vaccine booster dose (0.3 mL) may be administered at least 6 months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine to individuals 16 years of age and older.

A single booster dose of the Pfizer-BioNTech COVID-19 Vaccine may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

Adverse reaction:

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:

Anaphylaxis, hypersensitivity.

Psychiatric disorders:

Insomnia.

Nervous system disorders:

Headache, dizziness, hypoesthesia acute peripheral facial paralysis.

Gastrointestinal disorder common:

Nausea, vomiting, diarrhea.

Musculoskeletal and connective tissue disorder:

Arthralgia, myalgia and pain in extremity.

Cardiovascular disorder:

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

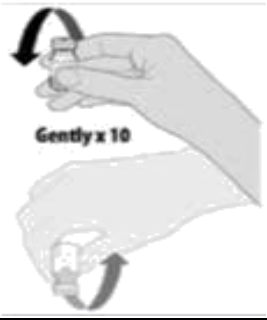
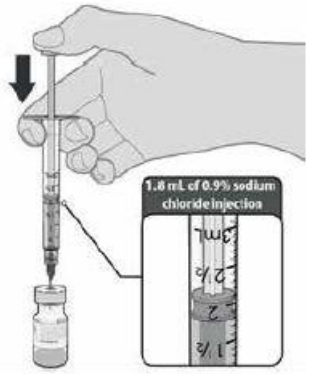
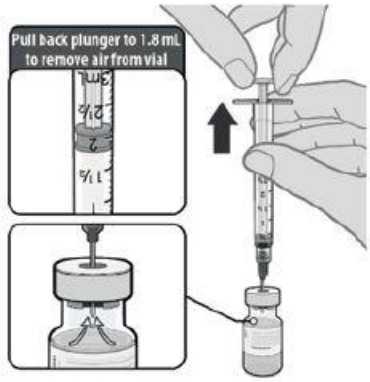
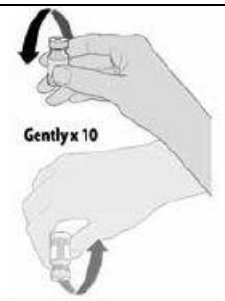
Observation time after vaccine administration:

There are 2 formulations of Pfizer-BioNTech COVID-19 Vaccine authorized for use in individuals 12 years of age and older **(purple and gray)** cap vials. The purple cap vials to be diluted before use while gray color cap vials are ready to use.

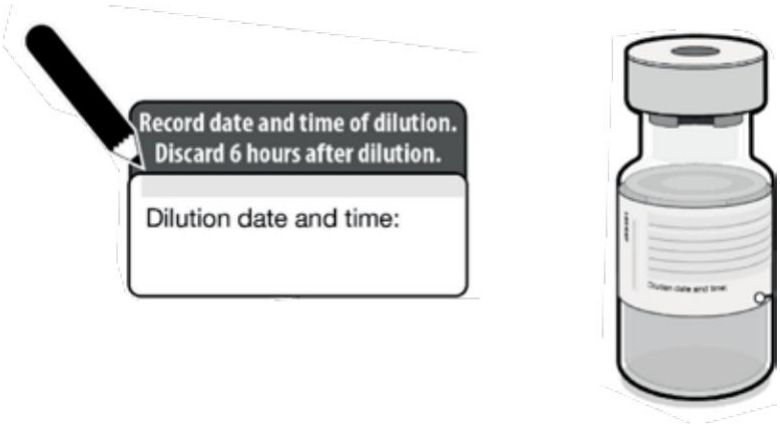
Vaccine recipients should be monitored for **15 minutes** after vaccination, with a longer observation period when indicated after clinical assessment.

Preparation:

- The multi-dose vial is stored frozen and must be thawed prior to dilution.
- Vials may be thawed in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] or at room temperature [up to 25ºC (77ºF)] (see Storage and Handling).
- Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.
- Dilute the vial contents using 1.8 mL of ONLY 0.9% Sodium Chloride Injection, USP to form the
  Pfizer-BioNTech COVID-19 Vaccine.
- Only use 0.9% Sodium Chloride Injection, USP as the diluent. The 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.
- After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a
- single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle.
- Each dose must contain 0.3 mL of vaccine.
  IfThe amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and content.
- Do not pool excess vaccine from multiple vials.
- 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.

DILUTE BEFORE USE	
	• Remove a thawed vial of Pfizer-BioNTech COVID-19 Vaccine from the refrigerator and allow it to come to room temperature. • If using a frozen vial of Pfizer-BioNTech COVID-19 Vaccine, thaw for 30 minutes at room temperature. Vials at room temperature must be diluted within 2 hours.
	• Invert gently 10 times to mix. • Do not shake.
	• Obtain sterile 0.9% Sodium Chloride Injection, USP. • Cleanse the vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the Pfizer-BioNTech COVID-19 Vaccine vial using a needle 21-gauge or narrower.
	• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • Do not shake.

	• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.



Special warnings, precautions and contraindication:

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:

- 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.
- A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of the vaccine.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.
- The administration of COVID-19 mRNA Vaccine BNT162b2 should be postponed in individuals suffering from acute severe febrile illness.
- The vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

- Immunocompromised persons (such as HIV patients), including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine.
- Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients. individuals may not be fully protected until 7 days after their second dose of vaccine.

Myocarditis and Pericarditis:

Reports of adverse events following use of the Pfizer-BioNTech COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly following the second dose. Typically, onset of symptoms has been within a few days following receipt of the Pfizer-BioNTech COVID-19 Vaccine. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms, but information is not yet available about potential long-term sequelae. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances.

Special population:

Emergency Use Authorization of this formulation of Pfizer-BioNTech COVID-19 Vaccine, supplied in multiple dose vials with purple caps, in adolescents 12 through 17 years of age is based on safety and effectiveness data in this age group and in adults.
For individuals 5 through 11 years of age, a different presentation and formulation of the Pfizer-BioNTech.
Pfizer-BioNTech COVID-19 Vaccine does not include use in individuals younger than 5 years of age.

Geriatric:

Clinical studies of Pfizer-BioNTech COVID-19 Vaccine 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.
- In a reproductive and developmental toxicity study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (30 mcg) and other ingredients included in a single human dose of Pfizer-BioNTech COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.
- 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.

Interaction:

Concomitant administration of COVID-19 mRNA Vaccine BNT162b2 with other vaccines has not been studied. Do not mix COVID-19 mRNA Vaccine BNT162b2 with other vaccines/products in the same syringe.

Storage and handling:

- Frozen Vials Prior to Use

Cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container and preferably store in an ultra-low temperature freezer between -80ºC to -60ºC (-112ºF to -76ºF) until shelf life of vials which is 9 months from the manufacturing date. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80ºC to -60ºC (-112ºF to -76ºF). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

- Transportation of Frozen Vials

  If local redistribution is needed and full cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F). Any hours used for transport at -25°C to -15°C (-13°F to 5°F) count against the 2 weeks limit for storage at -25°C to -15°C (-13°F to 5°F). Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -80ºC to -60ºC (-112ºF to -76ºF).

- Thawed Vials Before Dilution

  Thawed Under Refrigeration.

  Thaw and then store undiluted vials in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for up to 31 days. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.

- Thawed at Room Temperature

  For immediate use, thaw undiluted vials at room temperature [up to 25ºC (77ºF)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.

Undiluted vials may be stored at room temperature for no more than 2 hours.

- **Transportation of Thawed Vials**

  Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours. Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 31 days limit for storage at 2°C to 8°C (35°F to 46°F).

- **Vials After Dilution**

  After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours.

  Do not refreeze.

- **Refer to SPC for further information.**

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.
- 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