Health care provider (HCP) Guide

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

- The objective of the Health Provider guide is to provide essentials 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.

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 16 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.

Posology and method of administration

Dosing and schedule

COVID-19 mRNA Vaccine BNT162b2 is administered intramuscularly after dilution as a series of two doses (0.3 mL each) 21 days apart.

There is no data available on the interchangeability of COVID-19 mRNA Vaccine BNT162b2 with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of COVID-19 mRNA Vaccine BNT162b2 should receive a second dose of COVID-19 mRNA Vaccine BNT162b2 to complete the vaccination series. Individuals may not be protected until at least 7 days after their second dose of the vaccine.

Method of administration

Administer the COVID-19 mRNA Vaccine BNT162b2 vaccine intramuscularly in the deltoid muscle after dilution.

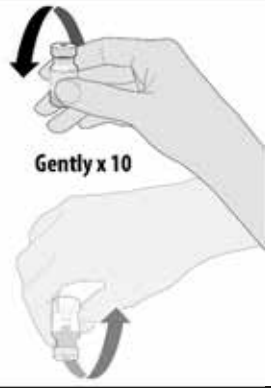
Do not inject the vaccine intravascular, subcutaneously or intradermal.

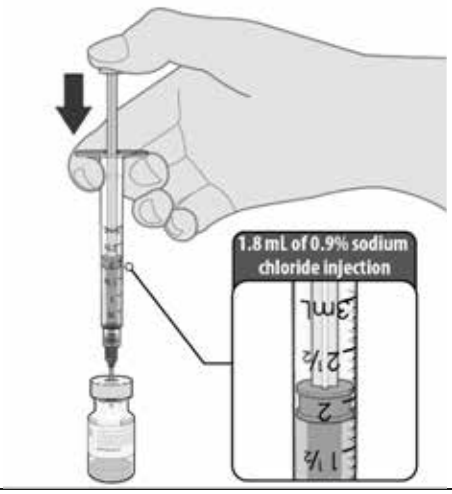
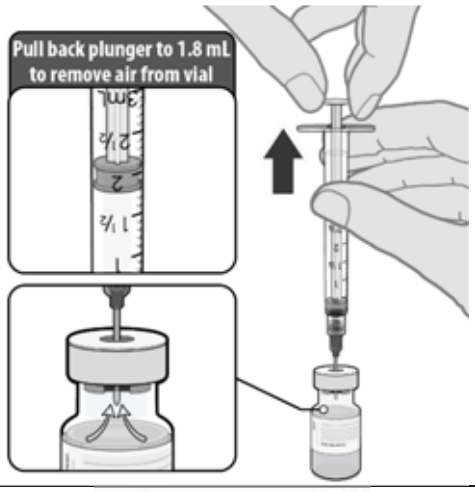
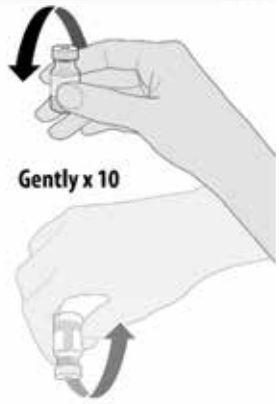
Observation time after vaccine administration:

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 [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, the vial contains five 0.3 mL doses of Pfizer-BioNTech COVID-19 Vaccine.
- 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. • <u>Do not shake</u>.
	• 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.

Special population:

- **Pediatric :** The safety and efficacy of COVID-19 mRNA Vaccine BNT162b2 in children under 16 years of age have not yet been established

  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.

- 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.

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

Nervous system disorders:
Headache
Acute peripheral facial paralysis

Gastrointestinal disorder common:
Nausea

Musculoskeletal and connective tissue disorder:
athralgia, myalgia and Pain in extremity

Storage and handling

- After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once thawed, the undiluted vaccine can be stored for up to 5 days at 2 °C to 8 °C, or up to 2 hours at temperatures up to 25 °C, prior to use. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
- After dilution, store the vaccine at 2 °C to 25 °C and use immediately and within 6 hours. The vaccine does not contain a preservative. Discard any unused vaccine.
- Once diluted, the vials should be marked with the dilution date and time. Once thawed, the vaccine cannot be re-frozen.
- 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.

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

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