

JOB AID FOR COVID-19 VACCINE ADMINISTRATION

Pfizer–BioNTech COVID-19 vaccine, BNT162b2

updated version: 04/10/2021

(International nonproprietary name: tozinameran)

1. GENERAL INFORMATION

- **Vaccine:** mRNA-vaccine, multidose vial containing 0.45 ml suspension (after mixing with 1.8 ml diluent contains up to 6 doses of 0.3 ml each)
- **Diluent:** 0.9% sodium chloride (normal saline, preservative-free); 1.8 ml per vaccine vial
- **Schedule:** 2 doses, 21-28 days apart*; a minimum interval of 14 days between administration of BNT162b2 and any other vaccine
- **Age indication:** 12 years of age and older
- **Route and site of administration:** Intramuscular of the deltoid muscle of the upper arm

* Countries that have not yet achieved high vaccination coverage rates in the high priority groups that are experiencing a high incidence of COVID-19 cases combined with vaccine supply constraints may extend the inter-dose interval up to 12 weeks to achieve high first-dose coverage in high priority groups.

2. STORAGE CONDITIONS AND SHELF LIFE OF VACCINE

STORAGE CONDITIONS	SHELF LIFE	
Unopened vaccine vials:		
-90 °C to -60 °C	9 months	<ul style="list-style-type: none"> • Avoid exposure to direct sunlight and ultraviolet light
Other conditions, if within 9-month shelf life:		
-25 °C to -15 °C	Up to 2 weeks*	<ul style="list-style-type: none"> • Vials stored at -25 °C to -15 °C for up to 2 weeks may be returned one time to the recommended storage condition of -90 °C to -60 °C. NOTE: Total cumulative time the vials are stored at -25°C to -15°C should be tracked and should not exceed 2 weeks!
+2 °C to +8 °C	Up to 31 days**	<ul style="list-style-type: none"> • Thawed undiluted vials stored at 2-8°C can be stored for 31 days.
Room temperature up to +30 °C	Up to 2 hours	<p>➔ NOTE: Total cumulative time the vials are stored at +2 °C to +8 °C should be tracked and should not exceed 31 days!</p> <ul style="list-style-type: none"> • Thawed vials can be handled in room light conditions.
Diluted vaccine vials:		
+2°C to +30°C	Up to 6 hours	<ul style="list-style-type: none"> • Diluted vaccine vials can be handled in room light conditions. • Opened vaccine vials should be discarded at the end of the immunization session, or within 6 hours after opening, whichever comes first.

*Update the expiry date on the secondary packaging when moving unopened vials to -25 °C to -15 °C (updated expiry date: 2 weeks from date when moving vials to -25 °C to -15 °C).

** Update the expiry date on the secondary packaging when moving unopened vials to +2 °C to +8 °C (updated expiry date: 31 days from date when moving vials to +2 °C to +8 °C).

➔ **NOTE:** Ensure all vaccines and diluents are kept in their original secondary packaging and are clearly labelled

3. MATERIAL NEEDED FOR VACCINATION AND SUPPLIES

- Diluent: 0.9% sodium chloride (normal saline, preservative-free, 2 ml vial/ampoule)
- Syringe for diluent (2 to 5 ml syringe with 0.1 ml graduations) with a 21-gauge (or narrower) needle
- Syringe for vaccine administration (0.3 ml or 1 ml syringe with 0.1 ml graduations) with 23-gauge (or narrower) needle
- Sterile single-use antiseptic swabs
- Safety box for sharps disposal
- Medical treatment kits to manage allergic reactions in the event of an acute anaphylactic reaction
- Personal protective equipment (PPE) for vaccinators (gown, gloves, medical mask, face shield, goggles) as per the national

infection prevention and control guidelines

- Hand hygiene (alcohol-based hand rub or running water and soap) and surface cleaning agents

4. THAWING FROZEN VACCINE





Frozen vaccine vials may be thawed in the refrigerator or at room temperature.

→ **Note:** Record on the label the date of thawing. **Do NOT** refreeze thawed vaccine.

- **Thawing in refrigerator** (between +2 °C to +8 °C) may take 2 - 3 hours for 25 to 195 vials; fewer number of vials will take less time
- **Thawing at room temperature** (up to +30 °C) takes between 30 minutes and 2 hours; vials at room temperature must be mixed within 2 hours or returned to the refrigerator

5. PREPARATION FOR VACCINATION

→ **NOTE:** One diluted vaccine vial contains up to 6 doses of vaccine

1		<ul style="list-style-type: none">• Perform hand hygiene before vaccine preparation. Follow aseptic technique throughout vaccine preparation.
2		<p>→ NOTE: For vaccine preparation use EVERY TIME a NEW vaccine vial and NEW diluent vial.</p> <p>NEVER use expired vaccine or diluent. NEVER use thawed vaccine kept at +2 °C to +8 °C beyond 31 days.</p> <ul style="list-style-type: none">• Remove thawed vaccine vial from the refrigerator.• Allow thawed vaccine to come to room temperature (up to +30 °C) before dilution.
3		<ul style="list-style-type: none">• When the vaccine is at room temperature, gently invert vial 10 times. Do NOT shake the vial.• The vaccine is white to off-white in colour and may contain opaque particles. <p>→ Note: If the vaccine vial is shaken, discard the vaccine vial. Do not use if liquid is discoloured or if other particles are observed.</p>
4		<ul style="list-style-type: none">• Wipe off the stopper of the <u>diluent vial</u> using a NEW, sterile single-use antiseptic swab.• Wipe off the stopper of the <u>vaccine vial</u> using a NEW, sterile single-use antiseptic swab.• Using a NEW, sterile 21-gauge (or narrower) needle, withdraw 1.8 ml diluent from the diluent vial into a NEW, sterile mixing syringe.• Discard diluent vial and any remaining diluent.
5		<ul style="list-style-type: none">• Inject the 1.8 ml diluent into the vaccine vial.• Remove 1.8 ml of air from the vaccine vial using the mixing syringe to equalize the pressure in the vaccine vial.
6		<ul style="list-style-type: none">• Discard the mixing syringe with the needle (don't recap the needle). Do NOT leave the needle in the stopper of the vial!
7		<ul style="list-style-type: none">• Gently invert the vaccine vial containing vaccine and diluent 10 times. Do NOT shake the vial.• The vaccine will be off-white in colour. <p>→ Note: If the vaccine vial is shaken, discard the vaccine vial. Do not use if liquid is discoloured or contains particulate matter.</p>
8		<ul style="list-style-type: none">• Write the date and time the vaccine was mixed on the vaccine vial.
9		<ul style="list-style-type: none">• Keep mixed vaccine at +2 °C to +30 °C and administer within 6 hours. Do not return vaccine to refrigerator or freezer storage.• Discard any unused vaccine at the end of the immunization session, or within 6 hours after opening, whichever comes first.

6. CONTRAINDICATIONS AND PRECAUTIONS









Contraindications

- History anaphylaxis to any component of the vaccine

Precautions

- History of anaphylaxis to any other vaccine or injectable therapy
- Persons with an immediate non-anaphylactic allergic reaction to the first dose of vaccine
- Acute febrile illness (body temperature >38.5 °C)
- 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

7. ADMINISTRATION OF VACCINE

1		<ul style="list-style-type: none"> Be sure to wear correct personal protective equipment (PPE) before administering vaccines. Ensure that the implemented policies for the use of face coverings for vaccine recipients are in place.
2		<ul style="list-style-type: none"> Assess recipient status: <ul style="list-style-type: none"> Screen for contraindications and precautions (see above). Review vaccination history: Which dosage will be administered (first/second)? Has any other vaccine been administered within the previous 14 days? If yes, discuss delaying of vaccination (a minimum interval of 14 days following other vaccines should be observed).
3		<ul style="list-style-type: none"> Place patient in sitting position, looking to the other side.
4		<ul style="list-style-type: none"> Choose the correct equipment for vaccine administration: NEW sterile syringe for vaccine with NEW sterile 23-gauge (or narrower) needle. Use a NEW, sterile needle and syringe for each injection.
5		<ul style="list-style-type: none"> Wipe of the stopper on the mixed vaccine vial using a NEW, sterile single-use antiseptic swab. Withdraw 0.3 ml of mixed vaccine into the syringe. Remove any air bubbles with the needle still in the vial to avoid loss of vaccine. Confirm there are no particulates and that no discolouration is observed. <p>→ NOTE: The same needle to withdraw and administer the vaccine can be used, unless contaminated or damaged.</p>
6		<ul style="list-style-type: none"> Ensure the prepared syringe is not cold to the touch. <ul style="list-style-type: none"> Ensure the liquid in the syringe is <i>white to off-white</i> in color, with clear to slightly opaque suspension. Ensure the vaccine volume in the syringe is 0.3 ml. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
7		<ul style="list-style-type: none"> Administer the vaccine immediately by intramuscular injection in the deltoid muscle of the upper arm.
8		<ul style="list-style-type: none"> Discard the used syringe into the safety box or safe syringe container (without recapping the needle).
9		<ul style="list-style-type: none"> Observe recipients after vaccination for an immediate adverse reaction: <ul style="list-style-type: none"> 30 minutes: persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause 15 minutes: all other persons
10		<ul style="list-style-type: none"> Document the vaccination: Provide a document recording date and product of vaccination. Indicate if applicable the date of the second dose.
11		<ul style="list-style-type: none"> Report any suspected adverse reactions according to the national procedures.

8. MANAGEMENT OF ANAPHYLAXIS AND ANXIETY-RELATED REACTIONS

Events of anaphylaxis and anxiety-related reactions may occur. The vaccine should be administered only in settings where anaphylaxis can be treated. Make sure that a health care worker competent in identifying and treating these reactions and necessary equipment and medications are available. Take precautions to avoid injury from fainting.

9. MYOCARDITIS AND PERICARDITIS

Very rare cases of myocarditis and pericarditis have been observed following vaccination with the mRNA COVID-19 vaccines. These cases occurred more often in younger men and after the second dose of the vaccine, typically within few days after vaccination. Current evidence suggests a likely causal association between myocarditis and the mRNA vaccines. The risk of myocarditis and pericarditis is very low and the benefits of mRNA COVID-19 vaccines in reducing hospitalizations and deaths due to COVID-19 infections outweigh the risks.

Clinicians should instruct vaccinated individuals to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as new onset and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare providers should report all myocarditis and other adverse events observed following administration of mRNA or other vaccines.

10. COMMUNICATION DURING VACCINATION VISIT



1	<p>Explain the benefits of the vaccine</p> <p>“The COVID-19 vaccine is a safe way to protect yourself from the COVID-19 (coronavirus) disease.”</p>						
2	<p>Enquire about and screen for contraindications and precautions</p> <p>“We want to make sure it will be safe for you to receive the vaccine.” <i>[Ask about the contraindications and precautions listed above.]</i></p>						
3	<p>Explain the process</p> <p>“The vaccine is given through an injection into your shoulder. You may feel a slight pinch when the needle goes in. Afterwards, we want you to stay here for <i>[15 or 30 minutes, depending on patient history]</i> to be sure you don’t have any allergic reactions.</p>						
4	<p>Explain the common side effects</p> <p>“We want you to be aware of some common side effects of the vaccine. <i>[Explain common and rare side effects.]</i> You might have some redness and soreness at the injection site, or you might have a mild fever and body aches. These usually improve within a few days after vaccination, but if for some reason they last longer contact health care professionals.</p>						
5	<p>Resolve concerns and answer questions</p> <p>Listen actively to show interest and concern and ask about any questions or concerns about receiving the COVID-19 vaccine.</p> <ul style="list-style-type: none"> • Respond with empathy and understanding. • Offer positive encouragement. • Be respectful and avoid arguing. 						
<table border="1"> <thead> <tr> <th style="text-align: left;">Common patient concerns</th> <th style="text-align: left;">Example responses from health workers</th> </tr> </thead> <tbody> <tr> <td>“I am worried about the possible side effects.”</td> <td>“I understand that you want to make the best choice for yourself. What potential side effects are you concerned about?” <i>[Address as appropriate]</i></td> </tr> <tr> <td>“I am not sure what to do. I have heard and read so many things about the vaccine that I don’t know what to believe.”</td> <td>“I understand that so much contradictory information can be confusing. I am happy to answer your questions and also refer you to trustworthy sources of information online.”</td> </tr> </tbody> </table>		Common patient concerns	Example responses from health workers	“I am worried about the possible side effects.”	“I understand that you want to make the best choice for yourself. What potential side effects are you concerned about?” <i>[Address as appropriate]</i>	“I am not sure what to do. I have heard and read so many things about the vaccine that I don’t know what to believe.”	“I understand that so much contradictory information can be confusing. I am happy to answer your questions and also refer you to trustworthy sources of information online.”
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6	<p>Inform about the necessary follow-up</p> <p>Remember that you will still need to have a second injection of the COVID-19 vaccine in about 3-4 weeks. Please make an appointment for that time so we can give you the second injection.”</p>						

11. SOURCES

1. World Health Organization. Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing. Updated 15 June 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1)
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5. World Health Organization. Recommendation for an emergency use listing of tozinameran (COVID-19 MRNa vaccine (nucleoside modified) submitted by BioNTech Manufacturing GmbH (https://extranet.who.int/pgweb/sites/default/files/documents/TAG-EUL_PublicReport_BioNTech_DEC20.pdf)
6. WHO Aide-memoire: infection prevention and control (IPC) principles and procedures for COVID-19 vaccination activities, 15 January 2021: <https://apps.who.int/iris/handle/10665/338715>

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