

Pfizer-BioNTech COVID-19 Vaccine Information

- COVID-19 vaccines should not be administered at the same time as any other live or inactivated vaccine, due to the potential for immune interference and the need to be able to monitor for potential symptoms of COVID-19 and COVID-19 vaccine adverse events without potential confounding from adverse events following other vaccines.
- Please wait a minimum of 14 days following the administration of another vaccine before administering a COVID-19 vaccine and 28 days after the administration of the complete two-dose series of an mRNA COVID 19 vaccine before the administration of another vaccine
- If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated

	PFIZER-BIONTECH COVID-19 mRNA Vaccine
Eligible population	This vaccine is being offered in a phased approach. Please follow operational guidelines to assess eligibility.
Dose and Schedule	<p>Each dose is 0.3 mL IM in the <u>deltoid muscle</u> (preferred site but vastus lateralis can be used as an alternate if required)</p> <p>2 dose series:</p> <ul style="list-style-type: none"> • Dose 1: day 0 • Dose 2: day 21 (recommended but 19-42 days is acceptable)* <p>Please note:</p> <ul style="list-style-type: none"> • Minimal interval of 19 days between doses • If administration of the second dose is delayed, the second dose should be provided as soon as possible. Currently, no data on a maximum interval between doses or on medium- or long-term efficacy of COVID-19 vaccines are available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series. • COVID-19 vaccines are NOT interchangeable. The vaccine series should be completed with the same COVID-19 vaccine product <p>*Administration of the second dose to those in LTCFs and PCHs is to continue as per product monograph spacing</p>
Components (Consult product monograph for complete listing of the non-medicinal ingredients and excipients)	<p>mRNA (new technology) – nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein(s), formulated in lipid nanoparticles (LNPs)</p> <p>Lipids nanoparticles (these help the mRNA enter the cell):</p> <ul style="list-style-type: none"> • ALC-0315 = (4-hydroxybutyl) azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) • ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide <p>Other Lipids: (provide structural integrity of the nanoparticles)</p> <ul style="list-style-type: none"> • 1,2-distearoyl-sn-glycero-3-phosphocholine • Cholesterol • Salts: (help maintain the vaccine pH) • bibasic sodium phosphate dihydrate • monobasic potassium phosphate • potassium chloride • sodium chloride <p>Other:</p> <ul style="list-style-type: none"> • sucrose (protects the nanoparticles when frozen) • water for injection
Potential Allergen	polyethylene glycol (PEG)
Adjuvant	No
Thimerosal	No
Latex	No
Antibiotics	No
Normal and Expected Reactions	<p><u>Very Common (≥1/10)</u></p> <ul style="list-style-type: none"> • injection-site pain, fatigue, chills, fever, headache, arthralgia, myalgia <p><u>Common (≤1/100 to <1/10)</u></p> <ul style="list-style-type: none"> • redness or swelling at injection site, nausea, diarrhea <p><u>Uncommon (≥1/1000 to <1/100)</u></p> <ul style="list-style-type: none"> • malaise, lymphadenopathy, vomiting <p>Fever was very common after administration of the second dose of the currently authorized mRNA COVID-19 vaccines.</p>

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Pregnancy	<ul style="list-style-type: none"> The safety and efficacy of Pfizer-BioNTech COVID-19 Vaccine in pregnant women have not yet been established COVID-19 vaccine is generally not recommended to individuals who are pregnant until after completion of pregnancy <ul style="list-style-type: none"> However, a complete series of COVID-19 vaccine may be offered, in consultation with the individual's physician, to pregnant individuals in the eligible group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. If the client has not discussed the vaccination with their Health Care Provider, please see further guidance provided in the <u>COVID-19 VACCINE PRECAUTIONS, RECOMMENDATIONS AND SCRIPTS</u> document for more information and direction. It would be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 Vaccine.
Lactation	<ul style="list-style-type: none"> It is unknown whether Pfizer-BioNTech COVID-19 Vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded Any COVID-19 vaccine is generally not recommended for individuals who are breastfeeding. <ul style="list-style-type: none"> However, a complete series of COVID-19 vaccine may be offered, in consultation with an individual's physician, to individuals in the eligible group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. If the client has not discussed the vaccination with their Health Care Provider, please see further guidance provided in the <u>COVID-19 VACCINE PRECAUTIONS, RECOMMENDATIONS AND SCRIPTS</u> document for more information and direction.
Immunocompromised and Auto-Immune Conditions	<ul style="list-style-type: none"> At this time, there is an absence of evidence on the use of COVID-19 vaccine in immunocompromised individuals and those with auto-immune conditions. COVID-19 vaccine is generally not recommended for populations who are immunosuppressed due to disease or treatment or those with an auto-immune disorder until further evidence is available, as there is a lack of evidence on efficacy and safety in this group. <ul style="list-style-type: none"> However, a complete series of COVID-19 vaccine may be offered, in consultation with the individual's physician, to individuals in the eligible group in this population if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. If the client has not discussed the vaccination with their Health Care Provider, please see further guidance provided in the <u>COVID-19 VACCINE PRECAUTIONS, RECOMMENDATIONS AND SCRIPTS</u> document for more information and direction.
Precautions	<ul style="list-style-type: none"> The safety and efficacy of Pfizer-BioNTech COVID-19 Vaccine in individuals under 16 years of age has not yet been established. Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. Administration should be postponed in individuals suffering from acute severe febrile illness. Monoclonal Antibodies or Convalescent Plasma as part of COVID-19 treatment <ul style="list-style-type: none"> Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of their COVID-19 treatment. Based on the estimated half-life of such therapies, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, immunization should be deferred for at least 90 days as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who receive passive antibody therapy before receiving any vaccine doses, as well as those who receive passive antibody therapy after their first dose but before their second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy

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	<ul style="list-style-type: none"> Antibody Therapies not specific to COVID-19 treatment <ul style="list-style-type: none"> For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of mRNA COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective vaccine antibody response. Thus, there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination.
Contra-indications	<ul style="list-style-type: none"> Known severe hypersensitivity to any component of the vaccine. Anaphylaxis to previous dose of COVID-19 mRNA vaccine. One non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
Presentation	<p><u>Vaccine</u></p> <ul style="list-style-type: none"> This vaccine is a white to off-white frozen suspension provided as a multiple dose vial and <u>must be diluted before use.</u> When thawed: may contain white to off-white opaque particles When thawed and reconstituted: off-white solution with no visible particulates. One vial contains 5 doses of 0.3mL of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles). <p><u>Diluent</u></p> <ul style="list-style-type: none"> Diluent is provided in 10 mL plastic vials (latex-free, preservative-free). Packaged in cartons of 25 vials and can be stored at room temperature. Diluent is single use. Once the 1.8 mL required is drawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It cannot be used to dilute multiple vials of vaccine.
Post-puncture shelf life	<p>Thawed, punctured vials</p> <ul style="list-style-type: none"> ThePfizer-BioNTech COVID-19 vaccine can be stored between +2°C to below +25°C but must be discarded after 6 hours from the time of first puncture. During storage, vials should be protected from light.

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Instructions for Administration	<p>RECONSTITUTION is required</p> <p>The Pfizer-BioNTech COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.</p> <p>Thaw vaccine before use:</p> <p>The frozen vial contains 0.45 mL and will need to be thawed before dilution.</p> <ul style="list-style-type: none"> Vials may be thawed in the refrigerator (2°C to 8°C) or at room temperature (up to 25°C). <ul style="list-style-type: none"> Thaw for 30 minutes at room temperature. (Vials at room temperature must be diluted within 2 hours.) Thaw for 3 hours in the refrigerator; and allow the vial to come to room temperature before dilution. <p>Dilute before use:</p> <ol style="list-style-type: none"> Before dilution, invert gently 10 times to mix. Do not shake. Dilution with sterile 0.9% Sodium Chloride Injection is required. (Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.) Cleanse the vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, into the Pfizer-BioNTech COVID-19 Vaccine vial using a needle 21-gauge or narrower. <ul style="list-style-type: none"> Diluent is single use. Once the 1.8 mL required is drawn from the diluent vial and added to the antigen vial, the diluent vial MUST be discarded. It cannot be used to dilute multiple vials of vaccine. Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe. <ul style="list-style-type: none"> This is to prevent any vaccine loss through spraying out due to higher pressure. Gently invert the vial again 10 times to mix. Do not shake. Inspect the vial to confirm there are no particulates and no discoloration is observed. Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. Store between 2°C to 8°C. Discard any unused vaccine 6 hours after dilution. Using vaccine contents from more than 1 vial to make a complete dose is not acceptable practice for vaccines preparation or administration. <p>Notes: Pre-loading vaccine into syringes is not recommended. The immunizing health practitioner should draw up each vaccine dose at the time of administration.</p> <p>Do not shake.</p>
Storage and Handling	<p>Frozen vials prior to use</p> <p>The Pfizer-BioNTech COVID-19 vaccine should be stored at temperatures of -80°C to -60°C and protected from light in the original packaging for up to 6 months</p> <p>If an ultra-low temperature freezer is not available, the thermal container in which the vaccine arrives may be used as temporary storage up to 30 days when consistently refilled to the top of the container with dry ice every 5 days.</p> <p>Thawed, unpunctured vials</p> <ul style="list-style-type: none"> Prior to dilution, thawed vials can be stored: <ul style="list-style-type: none"> in the refrigerator at 2°C to 8°C for up to 5 days, or at room temperature for no more than 2 hours. Do not refreeze. After thawing and mixing with 0.9% sodium chloride diluent, the vaccine can be stored at 2°C to 8°C for up to 6 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. <p>After dilution, the vaccine vials can be handled in room light conditions.</p>