The vaccine is not registered in Israel but was approved for use under Regulation 29(a) of the Pharmacists' Regulations (Preparations) 1986.

Please see the Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information on important treatment considerations for the Pfizer-BioNTech COVID-19 Vaccine via the following link: https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine. In the event this link does not work, please access the product's approved Fact Sheet, including Prescribing Information, at www.pfizer.com. Note: select fact sheet or prescribing information is excerpted further in the document.

Please note, some information in this letter is based on non-Israeli prescribing information.

The use of COVID-19 mRNA Vaccine BNT162b2 should be in accordance with official MoH guidance which are available in the following link:

Israel Ministry of Health: "Coronavirus (COVID-19) vaccines" National Immunization Guidelines, Epidemiology Department., December 2020.

WHAT ARE THE CONTRAINDICATIONS FOR THE PFIZER-BIONTECH COVID-19 VACCINE?
WHAT ARE THE WARNINGS & PRECAUTIONS FOR THE PFIZER-BIONTECH COVID-19 VACCINE ?

Select Emergency Use Authorization Prescribing Information

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 Description]*.[1]

Warnings and Precautions

Management of Acute Allergic Reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine.[1]

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer BioNTech COVID-19 Vaccine.[1]

Limitation of Effectiveness

The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.[1]

Description

The Pfizer-BioNTech COVID-19 Vaccine is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.[1]

Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.[1]

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative. The vial stoppers are not made with natural rubber latex.[1]

For further information regarding the authorized use under the Emergency Use Authorization (EUA), please refer to the Fact Sheet for Vaccination Providers Administering Vaccine or EUA Prescribing Information for the Pfizer-BioNTech COVID-19 Vaccine.

Literature Search

As of November 30, 2020, a search of the published medical literature failed to identify any data regarding the contraindications, warnings and precautions of the Pfizer-BioNTech COVID-19 Vaccine(also known as BNT162b2)).

Pfizer Medical Information is not aware of any additional information available on this topic at this time.

RECOMMENDATIONS

Advisory Committee on Immunization Practices (ACIP)

In the United States, the CDC's Advisory Committee on Immunization Practices (ACIP) provides recommendations regarding the routine administration of vaccines to children and adults.
For more information on ACIP, you can refer to their website at:
http://www.cdc.gov/vaccines/acip/index.html

INTERIM CLINICAL CONSIDERATIONS FOR USE OF PFIZER-BIONTECH COVID-19 VACCINE

The ACIP has released interim clinical considerations for use of mRNA COVID-19 Vaccines currently authorized in the United States. This information can be accessed at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fclinical-considerations.html

Regarding contraindications and precautions, the following is stated:[2]

> *While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. Although investigations are ongoing, persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis upon re-exposure to either of the currently authorized mRNA COVID-19 vaccines. For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.*
>
> *Recommendations for contraindications and precautions are described below and summarized in Appendix A. The following recommendations may change as further information becomes available.*
>
> *Contraindications*
>
> *CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:*

- *Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components*
- *Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])**
- *Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)**

> ***These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). See Appendix B for more information on ingredients included in mRNA COVID-19 vaccines.***
>
> *Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose) (Appendix C).*

Healthcare personnel or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance.

Precautions

CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines. These persons should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered until further information on the risk of anaphylaxis is available. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination in these individuals:

- *Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)*
- *Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)*
- *Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago*

  Note: Vaccination is recommended for persons with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, persons with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.
- *The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies*
- *Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis*

Neither contraindications nor precautions to vaccination

Allergic reactions (including severe allergic reactions) not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates, such as food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. The vial stoppers of these mRNA vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy. In addition, as the mRNA COVID-19 vaccines do not contain eggs or gelatin, persons with allergies to these substances do not have a contraindication or precaution to vaccination.

Observation periods following vaccination (for persons without contraindications to

mRNA COVID-19 vaccines)

CDC recommends an observation period following vaccination with mRNA COVID-19 vaccines. 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 should be observed for 30 minutes. All other persons should be observed for 15 minutes.

The following is found in the Appendix of the interim Clinical Considerations for for Use of mRNA COVID-19 Vaccines currently authorized in the United States:

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15-minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, injectable therapies, or polysorbate, such as: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies **ACTIONS** • 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) • 15-minute observation period: All other persons	**ALLERGIES** • History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† or polysorbate, as these are contraindicated) **ACTIONS:** • Risk assessment • Consider deferral of vaccination and/or referral to allergist-immunologist • 30-minute observation period if vaccinated	**ALLERGIES** History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)# • Immediate allergic reaction of any severity to polysorbate^# **ACTIONS** • Do not vaccinate# • Consider referral to allergist-immunologist

* See Special Populations section for information on patient counseling in these groups

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

^ See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

Table from ACIP Interim Clinical considerations for for use of mRNA COVID-19 Vaccines currently authorized in the United States (January 2021)

Please note that Pfizer is independent of these recommendations.

REFERENCES

[1] Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccines including the Full EUA Prescribing Information. Pfizer/BioNTech

[2]. Advisory Committee on Immunization Practices (ACIP). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Centers for Disease Control and Prevention website (Available at: Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine | CDC (Last accessed January 2, 2021).