

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Gray Cap

Select Questions¹

Emergency uses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent have not been approved or licensed by FDA but have been authorized by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals aged 12 years and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheets at www.cvdvaccine-us.com.



Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)
NDC number:
Multiple Dose Vial:
59267-0304-1

For whom is the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent, authorized for emergency use?

Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for use in individuals 12 years of age and older as a single booster dose administered at least 2 months after either:

- completion of primary vaccination with any authorized or approved monovalent* COVID-19 vaccine, or
- receipt of the most recent booster dose with any authorized or approved monovalent* COVID-19 vaccine

*Monovalent refers to any authorized or approved COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

Can Pfizer-BioNTech COVID-19 Vaccine, Bivalent, be used for the primary series for individuals 12 years of age and older?

No. Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), is not authorized for primary series vaccination.

Selected Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

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, Bivalent.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

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Please see full Important Safety Information and Authorized Use on pages 3 and 4.

Before administration, please click or visit cvdvaccine-us.com to see EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) (Booster Dose 12 years of age and older), **DO NOT DILUTE, Gray Cap** and the Recipients and Caregivers Fact Sheet: (Primary Series and Bivalent Booster Dose 12 years of age and older).

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Gray Cap

Select Questions¹

How do I verify the Pfizer-BioNTech COVID-19 Vaccine, Bivalent vials?

Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine, Bivalent has a gray cap and a label with a gray border and that the vial label states Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).

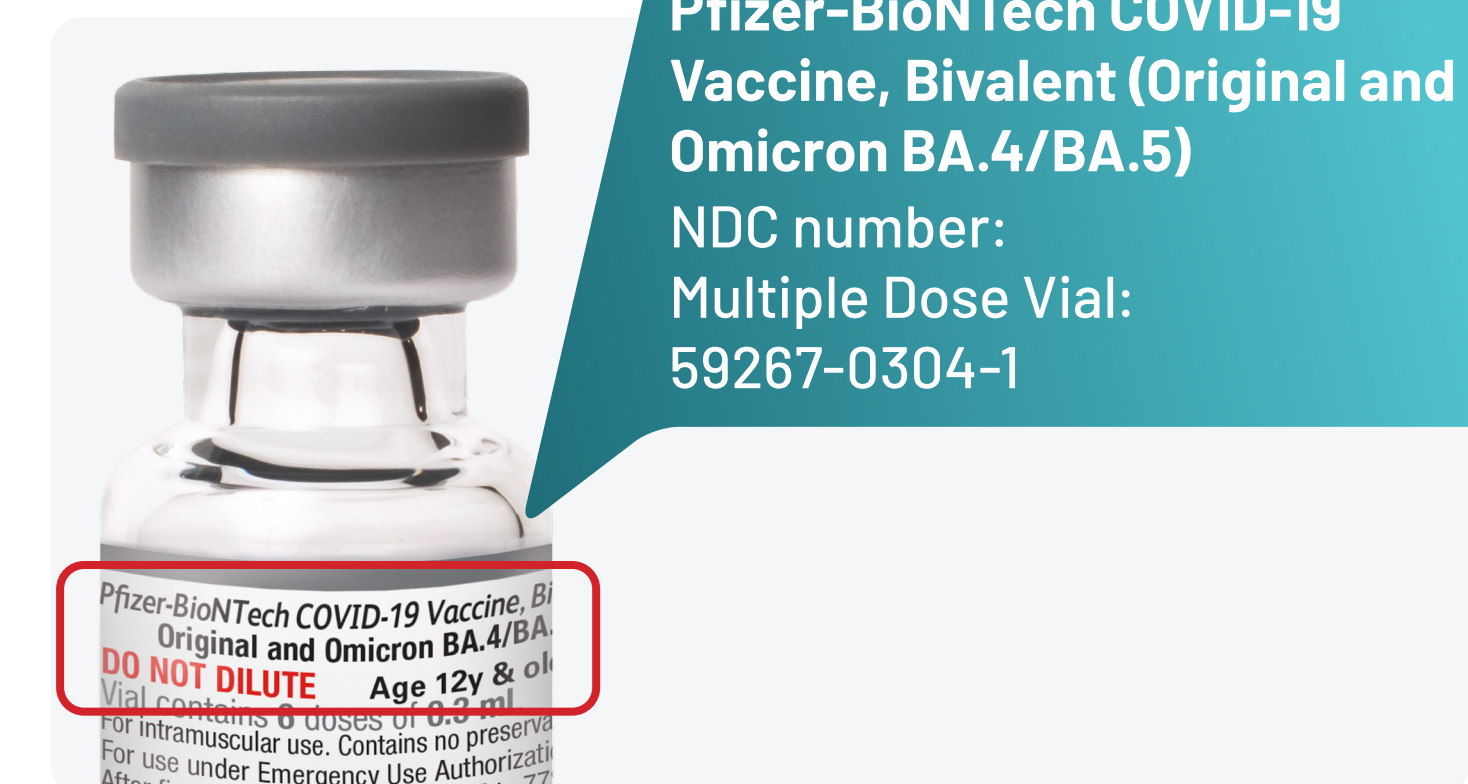
Click [here](#) or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) for the Formulation/Presentation Guide.

How do I prepare the vaccine for administration?

Please see section 2.1 of the [EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent \(Original and Omicron BA.4/BA.5\) \(Booster Dose 12 years of age and older\), DO NOT DILUTE, Gray Cap](#).

What are the NDC and CPT codes for Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)?

- The NDC code for Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) vial, is 59267-0304-1
- The CPT codes for Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), are 91312 (vaccine code) and 0124A (administration code)



Selected Safety Information

Myocarditis and Pericarditis

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

Postmarketing safety data with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

Postmarketing data with authorized or approved monovalent mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following receipt of the second primary series dose or first booster dose, with most booster doses likely administered at least 5 months after completing primary vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is higher among adolescent males and adult males under 40 years of age than among females and older males, and the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

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Please see full Important Safety Information and Authorized Use on pages 3 and 4.

Before administration, please click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to see [EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent \(Original and Omicron BA.4/BA.5\) \(Booster Dose 12 years of age and older\), DO NOT DILUTE, Gray Cap](#) and the [Recipients and Caregivers Fact Sheet: \(Primary Series and Bivalent Booster Dose 12 years of age and older\)](#).

Important Safety Information and Authorized Use

Important Safety Information

Do not administer Pfizer-BioNTech COVID-19 Vaccine, Bivalent to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of Pfizer-BioNTech COVID-19 Vaccine or Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

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, Bivalent.

Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

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Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

Altered Immunocompetence

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

Limitation of Effectiveness

Pfizer-BioNTech COVID-19 Vaccine, Bivalent may not protect all vaccine recipients.

Adverse Reactions

The safety of a booster dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent is based on:

- safety data from a clinical study which evaluated a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine (Original and Omicron BA.1), not authorized or approved, hereafter referred to as bivalent vaccine (Original and Omicron BA.1),
- safety data from clinical trials which evaluated primary and booster vaccination with Pfizer-BioNTech COVID-19 Vaccine, and
- post marketing safety data with Pfizer-BioNTech COVID-19 Vaccine.

The safety data accrued with the bivalent vaccine (Original and Omicron BA.1) and with Pfizer-BioNTech COVID-19 Vaccine are relevant to Pfizer-BioNTech COVID-19 Vaccine, Bivalent because these vaccines are manufactured using the same process.

The clinical study that evaluated a booster dose of the bivalent vaccine (Original and Omicron BA.1) included participants 55 years of age and older. Adverse reactions following administration of the bivalent vaccine (Original and Omicron BA.1) as a second booster dose included pain at the injection site (58.1%), fatigue (49.2%), headache (33.6%), muscle pain (22.3%), chills (13.0%), joint pain (11.3%), injection site redness (7.0%), injection site swelling (6.6%), fever (5.0%), lymphadenopathy (0.3%), nausea (0.3%), and malaise (0.3%).

Important Safety Information and Authorized Use (cont'd)

In a clinical study of participants 18 through 55 years of age, adverse reactions following administration of a first booster dose of Pfizer-BioNTech COVID-19 Vaccine were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%). Severe allergic reactions (including anaphylaxis), myocarditis, and pericarditis have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

Post Authorization Experience

Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions (eg, rash, pruritus, urticaria, angioedema), diarrhea, vomiting, pain in extremity (arm), and syncope have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine.

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

Additional adverse reactions, some of which may be serious, may become apparent with post authorization use of the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Authorized Use

Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

This EUA Prescribing Information pertains only to Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

Please see additional Important Safety Information on page 3.

Before administration of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), please click or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com) to see

[EUA Fact Sheet for Vaccination Providers, Pfizer-BioNTech COVID-19 Vaccine, Bivalent \(Original and Omicron BA.4/BA.5\) \(Booster Dose 12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[Recipients and Caregivers Fact Sheet: \(Primary Series and Bivalent Booster Dose 12 years of age and older\)](#)

Reference: 1. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), Bivalent (Original and Omicron BA.4/BA.5), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; August 31, 2022.



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Marketing Authorization Holder

Manufactured by
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New York, NY 10017

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

PP-CVV-USA-1440
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