

Pfizer/BioNTech COVID-19 vaccine, bivalent – Authorized as booster dose in 6 months – 4 years of age

- On March 14, 2023, the [FDA amended](#) the emergency use authorization (EUA) of the [Pfizer/BioNTech COVID-19 vaccine, bivalent](#) to provide for a single booster dose of the vaccine in children 6 months through 4 years of age at least 2 months after completion of primary vaccination with three doses of the monovalent (single strain) Pfizer/BioNTech COVID-19 vaccine.
 - Children 6 months through 4 years of age who completed their three-dose primary series with the monovalent Pfizer/BioNTech COVID-19 vaccine more than two months ago are now eligible to receive a single booster dose of the Pfizer/BioNTech COVID-19 vaccine, bivalent.
 - Since December 2022, children 6 months through 4 years of age who received the first two doses with monovalent Pfizer/BioNTech COVID-19 vaccine should complete their three-dose primary series with the Pfizer/BioNTech COVID-19 vaccine, bivalent. These children in this age group are not eligible for a booster dose of a bivalent vaccine at this time and are expected to have protection against the most serious COVID-19 outcomes. Today's authorization is for those children 6 months through 4 years of age who completed their 3-dose primary vaccination series with the monovalent Pfizer/BioNTech COVID-19 vaccine, before the Pfizer/BioNTech COVID-19 vaccine, bivalent was authorized to provide the third dose in the 3-dose primary series.
- The FDA evaluated immune response data from 60 children in this age group who had completed primary vaccination with three doses of monovalent Pfizer/BioNTech COVID-19 vaccine and received a booster dose of Pfizer/BioNTech COVID-19 vaccine, bivalent in a clinical study.
 - One month after receiving the Pfizer/BioNTech COVID-19 vaccine, bivalent, the study participants demonstrated an immune response to both the original SARS-CoV-2 virus strain and to omicron BA.4/BA.5.
- Safety data was evaluated in another study in children 6 months to 11 years of age who completed primary vaccination with three doses of monovalent Pfizer/BioNTech COVID-19 vaccine and received a booster dose of Pfizer/BioNTech COVID-19 vaccine, bivalent.
 - Among 24 participants 6 months through 23 months, the most common side effects included irritability, drowsiness, injection site redness, pain and swelling, decreased appetite, fatigue, and fever.
 - Among 36 participants 2 years through 4 years of age, the most common side effects included fatigue, injection site pain, redness and swelling, diarrhea, vomiting, headache, joint pain, and chills.
- After the Centers for Disease Control and Prevention (CDC) reviews and approves the FDA's amended EUA, updated information about Pfizer/BioNTech's bivalent booster for children 6 months to 4 years of age will be posted on the [CDC website](#).