Differences between the Adult/Adolescent and Pediatric Formulations

Pfizer-BioNTech COVID-19 Vaccines

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	Dilute Prior to Use	*Dilute Prior to Use*
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older

Orange Cap – Pediatric: Future authorization for aged 5- to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.

NOTE: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

****Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS***

*****The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old***

Pediatric Pfizer Vaccines

- Pediatric vials come packaged in cartons of 10 vials each. They have an orange cap and orange striping on the vial label as well as the carton. Each vial will contain 10 doses per vial after dilution.
- The pediatric dose is 0.2 mL of the diluted pediatric vaccine (orange cap).
- In addition to the orange cap and striping both the vial and the carton are labeled “For age 5 years to <12 years”

VaccineFinder

- Don’t forget to report your pediatric vaccine inventory in VaccineFinder so parents and caretakers are able to find locations where they may get children vaccinated.
- Remember to report all your Covid-19 Vaccine inventory to VaccineFinder daily. You can also report your flu availability.
- After 72 hours without reporting to VaccineFinder, your location will not appear in the search results.
- Reporting not only lets the public see where they can get vaccinated, it helps us with vaccine planning and distribution across the state, as well as being a requirement of your Covid-19 vaccine provider agreement.

Updated 11.9.21

Diluent

- Ancillary kits for the pediatric Pfizer orders will contain 10 mL diluent vials. These are larger than the small diluent vials previously available with the Pfizer ancillary kits.
- While they appear to contain sufficient diluent for multiple vials, they must only be used **once**.
    - **Diluent vials are a one-time use item and should be discarded with the remaining content after each use.**
    - **For each vial of vaccine, extract 1.3 mL of diluent from a single use vial.**
    - **Do not puncture the diluent vials more than once.**
- Pfizer recommends the use of a syringe with appropriate graduations to dilute with the directed 1.3 mL of saline. The impact to the final dose with a 1.2 or 1.4 mL dilution volume would be within 4% of the target dose. This suggests that using a syringe with 0.2 mL graduations and estimating the 1.3 mL volume will not significantly impact the intended dose.
- If a provider has a syringe in their inventory that they are more comfortable using, they may use this syringe to dilute the vaccine and replace syringes from their private supply with those from the ancillary supplies kit.

Storage Conditions

- Ultra-cold Freezer (-90°C to -60°C) for 6 months
- Refrigerator (2°C to 8°C) for 10 weeks
- They are **not** to be stored at freezer conditions (-25°C to -15°C) as the adult formula (purple cap) that you may currently have.
- After puncture, the pediatric vials can be stored at **2°C to 25°C** for up to **12** hours.

*Before administration of the vaccine, please see the EUA Fact Sheet for Vaccination Providers for 5 through 11 years of age (DILUTE PRIOR TO USE/**Orange cap**).*

Updated 11.9.21

Pfizer Expiration Date vs. Manufacturing Date

Pfizer COVID-19 Vaccine: 5 through 11 years of age formulation (orange cap) does NOT have an expiration printed on the vial. Instead, each vial has the lot number and date of manufacture printed on the label. Again, **the date on the label is NOT the expiration date.**

The QR code provided on the Pfizer Pediatric Vaccine carton provides a link to the EUA but does not provide information on expiration dates.

Pediatric Pfizer Shippers

- Pediatric doses will be shipped on dry ice in smaller disposable shippers.
- The shipper box **MUST** be unpacked immediately upon receipt. The contents should be placed in an ultra-cold freezer (-90°C to -60°C) or a refrigerator (2°C to 8°C). There will be an orange sticker on top of the shipper with a notice that the doses should not be stored in a standard freezer.
- Unlike the adult shippers you've been receiving, **these smaller shipper cannot be used for temporary storage**. The pediatric doses should not be stored in the previous Pfizer shipper that may be used as ultra-cold storage.

DDL in Pfizer Shippers

- Each Pfizer pediatric shipper includes a Controlant temperature monitoring device (DDL).
- This device cannot be used to continue temperature monitoring after delivery. Pediatric shippers are not intended to be used as temporary or long-term storage. Turn off the temperature monitor upon receipt and return it in the box provided.

Updated 11.9.21

Pfizer Pediatric Ancillary Kits

ACIP recommends a 22–25 gauge 1-inch needle when administering a vaccine by intramuscular injection to children 1 year of age and older. Vaccine administration guidelines are outlined here: ACIP Vaccine Administration Guidelines for Immunization | CDC and a chart summarizing needle length recommendations can be found here Vaccine Administration: Needle Gauge and Length (cdc.gov). Of note: A copy of this chart is included in each ancillary supply kit.

It is critical for all intramuscular injections that the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue. Some experts allow intramuscular injection with a ⅝-inch needle but **ONLY if the skin is stretched flat**. However, the most common technique when administering an IM injection is grabbing the muscle and bunching subcutaneous and muscle tissue to minimize the chance of striking bone, thus requiring a 1-inch needle or larger to ensure intramuscular administration. Studies have shown that use of longer needles is associated with less redness or swelling than occurs with shorter needles because of injection into deeper muscle mass, preventing irritation of the subcutaneous tissue.

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

Pfizer Vaccines US Medical Affairs continues to host daily *Medical Updates & Immunization Site Training for All Providers with a Focus on Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine for Children 5 through 11 Years of Age.*

In addition to Medical Updates, sessions will focus on the Storage, Handling, & Administration for currently available vaccine presentations**.**

These sessions will be **updated** to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation.

Please click on the links below to join the sessions at the designated times.*

Date & Time	Password
Attendee link – November 9 – 5 PM ET	aRDjkmMD349
Attendee link – November 10 – 12 PM ET	QPfX8RMy8M7
Attendee link – November 11 – 12 PM ET	Tntjh4UMr55
Attendee link – November 12 – 12 PM ET	mfP2vm8HhD5
Attendee link – November 15 – 5 PM ET	SUeJ7teYc45
Attendee link – November 16 – 5 PM ET	ZMjtfDdn438
Attendee link – November 17 – 12 PM ET	YYkSGJGT848
Attendee link – November 18 – 12 PM ET	8ZGbRrha2f8
Attendee link – November 19 – 12 PM ET	PzpX4ZPnT63
Attendee link – November 22 – 5 PM ET	YKwPs6P85cH
Attendee link – November 23 – 5 PM ET	S4wspGuhN33
Attendee link – November 24 – 12 PM ET	iWpzpvHh667