



Anticipated Emergency Use Authorization of Pfizer COVID-19 Vaccine for 5-11-year-olds October 15, 2021

As we anticipate the approval of EUA for the Pfizer COVID-19 vaccine for youth ages 5-11 years old, it is important to prepare our providers with new information ahead of the approval. This communication is intended to outline the key differences between the adult/adolescent formulation and the pediatric formulation.

The Pfizer-BioNTech vaccine for 5-11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC). **The current product for adults and adolescents should not be used in children.**


The table below provides the most current information on the upcoming pediatric formulation for the Pfizer-BioNTech COVID-19 Vaccine. The new pediatric vial will come with a distinctive ORANGE cap and be filled to 1.3mL before dilution. The pediatric formulation will continue to require addition of diluent and will contain 10 doses per vial.

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

The packaging configuration will be 10-dose vials in cartons of 10 vials each (100 doses total) pending FDA authorization. The product will be delivered in a newly updated product shipper at -80°C (-112°F).

Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C (36 – 46°F) and 6 months at ultracold temperatures of -90 to -60°C (-130 to -76°F).

The minimum order will be 300 doses initially and 100 doses in subsequent weeks. Shipment for pediatric vaccines can begin once FDA issues the EUA, and vaccine administration can begin once ACIP makes a recommendation.

Additional information will be released as it becomes available.

Should you have any questions, please call the Maine Immunization Program at 207-287-3746.