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**