

December 15, 2021

Dear COVID-19 Vaccination Program Provider,

We are writing with important information about changes to the Pfizer COVID-19 vaccine formulation for people ages 12 and older. Distribution of the new formulation, called Pfizer Tris Sucrose, will begin at the end of December. Pfizer Tris Sucrose has a distinctive gray cap, will not require dilution and will be available in 300-dose ordering quantities. This new formulation (Pfizer Tris Sucrose gray cap) will replace the current formulation (Pfizer purple cap) for people ages 12 and older.

Below is a table reviewing the storage and handling requirements for all of the Pfizer COVID-19 vaccine products. There are new storage, handling, and administration requirements for Pfizer Tris Sucrose-gray cap:

- The vaccine may be stored in an ultracold freezer between -90°C and -60°C (-130°F to -76°F) up to 6 months after the manufacture date and/or in a refrigerator between 2°C and 8°C (36°F to 46°F) for up to 10 weeks (within 6-months after manufacture date). The date listed on the vial is the manufacture date, **not** the expiration date.
 - To avoid administering vaccine after the beyond use date, label cartons and vials with beyond use dates when vaccine is first placed in ultracold freezer or refrigerator storage. If the vaccine is moved from the ultracold freezer to the refrigerator, update the label with the date and time and new beyond use date (up to 10 weeks). Vials should be relabeled when first punctured.
- The Pfizer thermal shippers **cannot** be used for temporary storage of this product and the vaccine **cannot** be stored in a regular freezer.
- Do not dilute Pfizer Tris Sucrose-gray cap prior to use.
 Once punctured, the vial must be discarded after 12 hours (the packaging may indicate 6 hours, but this has been updated in the FDA fact sheet).

Ensure all staff are trained on storage, handling, and administration of the new product before allowing them to do so. Require all staff to review the newest <u>FDA Fact Sheet</u>.

Pfizer purple cap vaccine will stop shipping on December 23, 2021. Beginning December 21, you will only have the option to order the Pfizer Tris Sucrose gray cap in the CIR Online Registry (www.nyc.gov/health/cir). This new vaccine will begin shipping nationwide on December 23, 2021. We are asking that providers deplete their inventory of Pfizer purple cap before ordering Pfizer Tris Sucrose gray cap. For larger volume sites, we recognize this may not be possible. To avoid mistakes, the two products should not be offered or administered at the same time. Providers with multiple vaccination sites should consider consolidating all remaining Pfizer purple cap vaccine at particular sites or transitioning one site at a time to ensure proper staff training and reduce the risk of storage, handling, and administration errors.

The New York City Department of Health and Mental Hygiene will be having three provider webinars to discuss these changes:

- Friday, December 17, 2021, 8:30 9:30 a.m. Register Here
- Tuesday, December 21, 2021, 12:30 1:30 p.m. Register Here
- Thursday, January 6, 2021, 3:00 4:00 p.m. Register here

Pfizer is updating their webinars in preparation for the launch of Pfizer Tris Sucrose gray cap. To access training sessions, visit https://www.pfizermedicalinformation.com/en-us/medical-updates.

We expect that Pfizer Tri Sucrose gray cap will enable more providers to participate in the COVID-19 vaccination program due to the simpler vaccine preparation instructions, more flexible refrigerator storage and smaller shipment sizes.

Please send questions to coviDVax@health.nyc.gov. Thank you for protecting the health of New Yorkers.

Sincerely,

Jane R. Zucker, MD, MSc Assistant Commissioner Bureau of Immunization

Description	Current Formulation	Future Formulations	
	Dilute Prior to Use	Do Not Dilute	Dilute Prior to Use
Age Group	12 years and older	12 years and older	5 to <12 years*
Vial Cap Color	PURPLE	GRAY	ORANGE
Dose	30 mcg	30 mcg	10 mcg
Injection Volume	0.3 mL	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	2.25 mL	1.3 mL
Amount of Diluent* Needed per Vial	1.8 mL	NO DILUTION	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)
Storage Conditions			
ULT Freezer (-90°C to -60°C)	9 months	6 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks	10 weeks

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