

Pfizer Tris Sucrose Adult/Adolescent Formulation Frequently Asked Questions for COVID-19 Vaccine Providers

The new **Pfizer Tris Sucrose adult/adolescent formulation (gray cap)** is now available for people age 12 years and older. The new formulation is packaged in smaller quantities, can be stored at standard refrigerator temperatures longer, and does not require dilution.

Ordering and Shipment

Q: Will this new gray cap vaccine replace the purple cap COVID-19 vaccine? If not, what is the difference?

A: Yes, the gray cap product will replace the purple cap product.

Q: Do we need to return the wasted full vials of COVID-19 vaccine to the Ohio Department of Health as we do for Vaccines for Children (VFC) vaccine?

A: Providers should dispose of expired COVID-19 vaccine waste in accordance with local regulations and processes used to dispose of regulated medical waste. For more information about disposing of medical waste, please visit the [Ohio EPA website](#).

Q: Is it delivered frozen?

A: Yes, Pfizer and Moderna vaccines are shipped frozen. Johnson & Johnson/Janssen (J&J) vaccine is shipped refrigerated.

Q: Does it ship with dry ice?

A: All Pfizer vaccine ships with dry ice. This includes shipments sent directly from the manufacturer and the Ohio Department of Health (ODH) Receipt, Store and Stage (RSS) Warehouse.

Q: Do we need to wait for the dry ice to totally dissolve before shipping back to ODH?

A: Please allow the dry ice to dissolve before returning a shipping container.

Q: Will the gray cap vaccine be sent in boxes similar to the orange cap instead of the large square boxes the purple cap vaccine came in?

A: The minimum quantity of Pfizer Tris Sucrose vaccine that can be shipped from the manufacturer is 300 doses. The shipper will include five boxes, each containing 60 doses.

Q: Is the smallest order for the pediatric formulation (orange cap) of Pfizer still 100 doses?

A: Yes. Pediatric Pfizer vaccine can be ordered from the COVID19 – Pfizer order set.

Q: We have ordered in 30-dose increments at a time. Is the smallest dose available now 100?

A: The smallest quantity of Pfizer Tris Sucrose vaccine that can be ordered is 60 doses. This vaccine is repackaged by the ODH RSS Warehouse. It is available in the COVID19 - ODH RSS order set.

Q: Will the state still be sending administration supplies with the 60-dose gray cap shipments?

A: All COVID-19 vaccine is shipped with ancillary supplies.

Q: Do we need to download the data logger that was in a container of ODH RSS shipped vaccine if it is blinking green?

A: For ODH RSS shipments that arrive with a possible temperature excursion, please contact the ODH COVID-19 Provider Call Center

at 1-844-963-4829 or email COVIDVACCINE@odh.ohio.gov for guidance from our customer service associates.

Q: Is there a new NDC number for the gray cap formulation?

A: GRAY cap NDC 59267-1025-04.

Q: Will there be a new Current Procedural Terminology (CPT) code?

A: CPT codes are developed and maintained by the American Medical Association (AMA) and are intended to support billing for services. An updated table of codes is available on the Centers of Disease Control and Prevention's [CPT Codes](#) webpage.

Q: With this new formulation, will the Vaccine Information Statement (VIS) change for the Pfizer vaccine, or is it still the same one?

A: The Emergency Use Authorization (EUA) fact sheets are the same. There are fact sheets for [healthcare providers](#) and for [recipients](#). We do not yet have a VIS for the COVID-19 vaccines.

Storage

Q: Could you clarify the storage of the gray and orange cap?

A: No regular freezer storage. The vaccine is valid for 9 months from manufacture when kept in an Ultra-Low Temperature (ULT) freezer. Once moved to the regular refrigerator, the vaccine must be used within 10 weeks. Keep in mind, the 10 weeks needs to be within the 9-month window of viability. Taking the vaccine from ULT freezer to regular refrigeration, potentially reduces the shelf life. It never increases it. If the vaccine is taken from ULT storage less than 10 weeks before the expiry date, it does not have 10 weeks available for use.

Q: Can we leave the Pfizer vaccine gray cap at room temperature for storage and for use for the 24-hour time frame?

A: Gray and orange cap may be stored at room temperatures for 12 hours prior to first puncture. Before first puncture, the vaccine can be returned to the refrigerator – the 12 hours is cumulative time. For instance, if the unpunctured vaccine is out for two hours and returned to the refrigerator, it has 10 hours left to be at room temperature. It must then be punctured and used within 12 hours or discarded. Be sure to use these vials first as they have decreased room temperature time. The 12 hours before puncture and 12 hours after puncture make for a total maximum time at room temperature of 24 hours.

Administration

Q: Do all doses need to be drawn up at the same time or can you draw up doses from the same vial, as needed, as long as you stay within the 12-hour time limit?

A: Ideally, each dose is drawn as needed and given immediately. However, the gray and orange cap presentations are viable for 12 hours after first puncture whether in the original vial or in syringes. The purple cap presentation is viable for six hours whether in the vial or syringe. Please protect from light, UV light and sunlight.

Q: When doing large clinics, we have people drawing up vaccine for us to use. This sometimes makes for medication to be in syringes for a short period of time prior to administering. Is this acceptable?

A: This is acceptable practice for mass vaccination clinics. You have a maximum of 12 hours from first puncture to administer the vaccine whether in the vial or syringes.

Q: Can the gray cap and the orange cap remain at room temperature for 12 hours?

A: The temperature requirements are the same for the gray and orange cap products. They can be left out at room temperature for 12 hours prior to first puncture and a maximum of 12 hours after first puncture.

Q: If gray and orange top are taken out of the refrigerator and not punctured, are they able to be placed back in the refrigerator?

A: Yes, they may go back into the refrigerator in that circumstance. The 12-hour room temperature is cumulative. If a vial was at room temperature for 4 hours and NOT punctured, it may be returned to the refrigerator, but it will be recorded as having only 8 hours remaining to be at room temperature.

Q: Is this correct? Both the orange and gray formulations could be removed from refrigeration, first punctured, and then left out of refrigeration at room temperature completely throughout the 12-hour maximum time period while additional doses are drawn.

A: Yes.

Q: Is there a higher volume of preservatives in the gray cap, which allows for the longer storage time? If so, are there any possible interactions/allergies we should be aware of?

A: The gray cap is preservative free. Expected side effects continue to be flu-like symptoms and local reactions at the injection site. Please see the [EUA](#) for a listing of ingredients.

Q: Are the purple and gray cap doses interchangeable? If they received purple cap, can they still receive gray cap as a booster?

A: Purple and gray cap vaccines are interchangeable. A vaccine series started with purple cap can be completed with gray cap. gray cap is replacing the purple cap. It has the advantages of longer storage and room temperature times and not requiring diluent.

Q: Does this new gray cap formula require a booster dose?

A: Yes. *Booster recommendations have not changed with the introduction of the gray cap formulation.*

Q: Is there a time requirement for pulling out of the refrigerator before giving the gray cap vaccine?

A: Vials need a minimum of 30 minutes out of the refrigerator or ULT freezer to come up to room temperature before administration. Whole cartons of vaccine from the ULT freezer can take as long as 6 hours to thaw in the refrigerator.

Q: First puncture of vial also includes the 30-minute thaw time, correct?

A: First puncture starts the 12-hour window where any unused vaccine must be used. At the 12-hour mark, the vaccine is no longer viable and must be discarded. Vaccine may be at room temperature for 12 hours before puncture.

Q: What is the dosage of the gray cap vaccine?

A: The dosage is the same as the purple cap vaccine it is replacing: 30mcg in 0.3mL injection volume.

Q: How many doses are contained in new gray top Pfizer vaccine vial?

A: Like the purple cap vaccine, the vial contains six doses.

Q: Is the gray cap light sensitive once punctured?

A: The vaccine should continue to be protected from once removed from storage. Pfizer recommends keeping the vials in the original carton. They do not have specific guidance for protecting the vaccine from light once drawn up into syringes. An opaque bag or cardboard box are some options for protection.

Q: Is the time between doses still 21 days for the gray cap product?

A: The interval between doses remains the same.

Wastage and Disposal

Q: Do we need to return the wasted full vial to ODH as we do for VFC vaccine?

A: Providers should **dispose of expired COVID-19 vaccine waste** in accordance with local regulations and processes used to dispose of regulated medical waste. For more information about disposing of medical waste, please visit the [Ohio EPA website](#).

Q: Should we dispose of full vials in biohazard waste and, if off-site at a clinic, should we dispose in sharps containers?

A: Sharps containers are an appropriate disposal container for single vials. Larger quantities of expired vaccine should be disposed of in accordance with local regulations and processes used to dispose of regulated medical waste. Cartons and vials should be defaced before disposal such that they are clearly no longer usable.

Q: Do we continue waste logs?

A: You can record wasted doses in the Vaccine Ordering and Management System (VOMS) via Inventory Reconciliation.

Resources:

- [How to Order COVID-19 Vaccine through VOMS](#)
- [Pfizer Fact Sheet for Healthcare Providers Administering Vaccine \(grey cap, 12 years and older\)](#)

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For additional information, visit coronavirus.ohio.gov.

If you have any questions or issues, please call the ODH Provider Call Center between 8 a.m. and 5:30 p.m. Monday through Friday at 1-844-9ODHVAX (1-844-963-4829) or email COVIDVACCINE@odh.ohio.gov.