



May 21, 2020

User Guide for Shipping Remdesivir from the Oregon Health Authority to Hospitals

Purpose: This user guide provides key information, tips, and best practices to assist Oregon and receiving hospitals during the last mile delivery of this critical product.

Background: Remdesivir was issued an [Emergency Use Authorization](#) on May 1, 2020, by the FDA for the treatment of coronavirus disease 2019 (COVID-19). The manufacturer, Gilead Sciences, Inc., has donated 940,000 vials of remdesivir for use in the United States. On May 2, Gilead sent initial supplies of remdesivir to AmerisourceBergen, the distributor for remdesivir.

AmerisourceBergen commenced shipment to identified hospitals upon receipt of the government's first allocation list on May 4. Shipments to state/territorial health departments and agencies (e.g., Indian Health Service; Veterans Health Administration) commenced on May 7.

Since May 7, states/territories/agencies that receive remdesivir have been determining how the product will be further allocated to hospitals within their jurisdictions.

A. Shipping information

- Oregon will ship vials of remdesivir via FedEx next day and courier service, depending on location. Before shipping, the Oregon Health Authority (OHA) will contact recipients directly and confirm the site can receive the package on a specific date. Shipments of remdesivir need to be refrigerated when the hospital receives them (2°C to 8°C [36°F to 46°F]) and used before they expire. If you have any questions or concerns about your shipment, please email ORES8.LogisticsChiefs@dhsosha.state.or.us.
- If desired, it is okay to ship partial cases from the state to hospitals as long as vials are appropriately packed, secured, and maintained at proper temperature
- Please see subsequent section for a sample shipping/receiving SOP

B. Product Information

- Remdesivir is available in two forms that have different storage/handling requirements (see subsequent section)
 - Remdesivir Injection (5 mg/ml) Concentrated Solution
 - Remdesivir Injection (100 mg) Lyophilized Powder
- For shipments initiated during May 7–May 17, states/territories/agencies received only the concentrated solution form of remdesivir
- Starting the week of May 18, states/territories/agencies will begin receiving the lyophilized powder form of remdesivir

- Additional shipments to states/territories/agencies are projected to occur in June and possibly later
 - From May 18 onward, shipments received by states/territories/agencies may contain concentrated solution only, lyophilized powder only, or both

Remdesivir Injection (5 mg/ml) Concentrated Solution (blue cap)

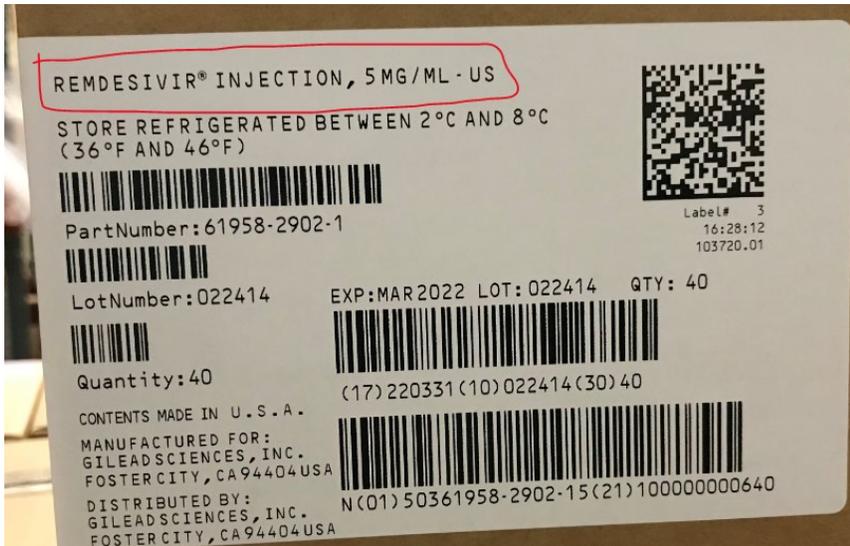


- **Must be stored at refrigerated temperature (2°C – 8°C [36°F to 46°F]) until use**
- Provided in boxed, single-dose 20 ml vials
 - Boxed vial dimensions: 2.3”(d) x 3.6”(h) x 2.0”(w)
- Shipped from AmerisourceBergen to states/territories/agencies in cases (40 vials/case)
 - Case dimensions: 12.1”(d) x 8.1”(h) x 8.9”(w)
 - Case weight: 5.3 lbs
- Earliest expiration date of vials shipped: 2/28/2022
- Detailed storage info below (copied verbatim from [Remdesivir Pharmacy Guide](#))

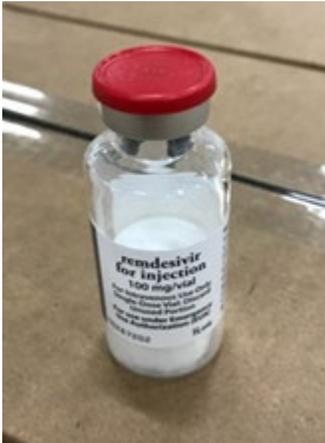
How should remdesivir be stored prior to use?

Injection Solution: Store remdesivir injection, 5 mg/mL, vials at refrigerated temperature (2°C to 8°C [36°F to 46°F]) until required for use. Do not use after expiration date. Dilute within the same day as administration. Prior to dilution, equilibrate remdesivir injection to room temperature (20°C to 25°C [68°F to 77°F]). Sealed vials can be stored up to 12 hours at room temperature prior to dilution. The concentrated solution must be diluted prior to use.

Sample Shipping Label for Case of Remdesivir Injection (5mg/ml) Concentrated Solution



Remdesivir Injection (100 mg) Lyophilized Powder (red cap)

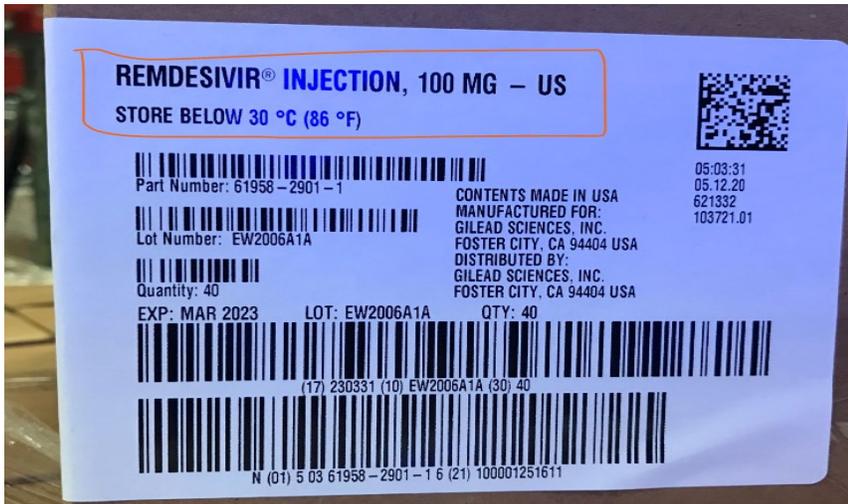


- Store at controlled room temperature (below 30°C [86°F]) until use
- Provided in boxed, single-dose vials
 - Boxed vial dimensions: 2.3”(d) x 3.6”(h) x 2.0”(w)
- Shipped from AmerisourceBergen to states/territories/agencies in cases (40 vials/case)
 - Case dimensions: 12.1”(d) x 8.1”(h) x 8.9”(w)
 - Case weight: 3.3 lbs
- Earliest expiration date of vials shipped: 03/31/2023
- Detailed storage info below (copied verbatim from [Remdesivir Pharmacy Guide](#))

How should remdesivir be stored prior to use?

Lyophilized Powder: Store remdesivir for injection, 100 mg, vials below 30°C (below 86°F) until required for use. Do not use after expiration date. The lyophilized powder must be reconstituted and diluted prior to use.

Sample Shipping Label for Case of Remdesivir Injection (100 mg) Lyophilized Powder



C. Patient planning information

- Treatment Courses
 - There are 2 remdesivir treatment courses
 - 5-day course (uses 6 vials, including loading dose on Day 1)
 - 10-day course (uses 11 vials, including loading dose on Day 1)
 - Per Gilead, averaged patient use is estimated to be 7.8 vials per treatment course (reflects balance between 5 and 10-day courses)
 - Each case (40 vials) estimated to provide 5.13 patient treatment courses
- Pediatric Administration
 - Per the [EUA Remdesivir Fact Sheet for Healthcare Providers](#) (Section 11.3, Pages 27-28), for pediatric patients with body weight between 3.5 kg and <40 kg, *use remdesivir for injection, 100 mg, **lyophilized powder only***
 - If lyophilized powder product is unavailable, it can be requested from Gilead through an [emergency investigational new drug \(EIND\) application](#) for pregnant women and children

D. Clinical Questions

- Refer to [EUA Remdesivir Fact Sheet for Healthcare Providers](#)
 - Gilead Medical Assist Line
 - AskGileadMedical.com
 - 1-866-MEDI-GSI (1-866-633-4474)
 - Monday–Friday, 6 AM to 4 PM PT

Standard Operating Procedures (SOP)

Shipping Remdesivir from Oregon Health Authority to Hospitals

1. Oregon Health Authority
 - a. Prior to receiving remdesivir from AmerisourceBergen (distributor of remdesivir)
 - i. Verify quantity and form(s) of remdesivir being shipped
 - ii. Verify adequate storage space (12" x 9" x 8" per case) at controlled room temperature for lyophilized powder or refrigeration (36°F - 46°F) for concentrated solution with the ability to monitor temperature for each
 - iii. Verify day/time of expected shipment arrival with shipper
 - b. Receipt of remdesivir from AmerisourceBergen
 - i. Document amount of medication received
 - ii. Put medication into proper storage area and maintain an inventory of receipt and dispensing
 - c. After determining which hospital is to receive medication
 - i. Obtain a point of contact person
 - ii. Verify the complete shipping address of the hospital pharmacy
 - iii. Verify the days and times that shipment can be accepted
 - iv. Identify and select a reliable shipping company that does cold chain shipping (e.g., FedEx, World Courier)
 - v. Pack product appropriately (12" x 9" x 8" per case)
 1. If sending a partial case, re-pack and secure vials in an insulated package (e.g., totes or boxes) with frozen gel-packs. Do NOT use dry ice as that is too cold.
 - vi. Arrange for transport paying attention to pick-up and delivery times
 - vii. Inform hospital pharmacy of shipping information
 - viii. Document receipt of product by hospital pharmacy
2. Hospitals
 - a. Prior to receiving remdesivir from the state/territory/agency
 - i. Verify adequate storage space (12" x 9" x 8" per case) at controlled room temperature for lyophilized powder or refrigeration (36°F - 46°F) for concentrated solution with the ability to monitor temperature for each
 - ii. Verify days and times that shipment can be accepted
 - b. Receipt of remdesivir from the state/territory/agency
 - i. Confirm receipt of product and document receipt of same as well as receipt at proper temperature
 - ii. Put medication into proper storage area while ensuring appropriate segregation and maintain an inventory of receipt and dispensing
 - c. Hospital Pharmacy
 - i. Segregate storage and develop inventory accountability record
 - ii. Ensure patient selection criteria for treatment is being followed
 - iii. Determine integration of treatment orders into hospital electronic medical record (EMR)

User guide template was created by the HHS Remdesivir Team. This user guide will be updated periodically. *Last updated May 21, 2020 by Oregon Health Authority.*

You can get this document free of charge in other languages, large print, braille or a format you prefer. Contact Mavel Morales at 1-844-882-7889, 711 TTY or OHA.ADAModifications@dhsosha.state.or.us.