

PRODUCT ORDERING GUIDE

PEMGARDA
(pemivibart) injection
for intravenous use

EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA™

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved product PEMGARDA for the pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
- Who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** are unlikely to mount an adequate response to COVID-19 vaccination.

LIMITATIONS OF AUTHORIZED USE

- PEMGARDA is not authorized for use:
 - For treatment of COVID-19, or
 - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90% based on available information including variant susceptibility to PEMGARDA and national variant frequencies.
- Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

PEMGARDA may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.

PEMGARDA has been authorized by FDA for the emergency use described above.

PEMGARDA is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

PEMGARDA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PEMGARDA under Section 564(b)(1) of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. § 360bbb 3(b)(1), unless the authorization is terminated or revoked sooner.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

- **Anaphylaxis has been observed with PEMGARDA in 0.6% (4/623) of participants in a clinical trial.**
- **Anaphylaxis was reported during the first and second infusion of PEMGARDA.**
- **Anaphylaxis can be life-threatening.**
- **Prior to administering PEMGARDA, consider the potential benefit of COVID-19 prevention along with the risk of anaphylaxis.**
- **Administer PEMGARDA only in settings in which healthcare providers have immediate access to medications to treat anaphylaxis and the ability to activate the emergency medical system (EMS), as necessary.**
- **Clinically monitor individuals during the infusion and for at least two hours after completion of the infusion.**
- **Discontinue PEMGARDA immediately if signs or symptoms of anaphylaxis or any severe systemic reaction are observed and initiate appropriate medications and/or supportive therapy.**

CONTRAINDICATIONS

PEMGARDA is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of PEMGARDA.

Please see additional Important Safety Information throughout and see the full [Fact Sheet for Healthcare Providers, including Boxed Warning](#) for more information on the EUA of PEMGARDA.



**PEMGARDA™
INFORMATION**

Product Concentration	500 mg/4 mL vial (125 mg/mL)
Package Size	9 vials per carton
Carton Contents	Each PEMGARDA carton contains a total dose (4500 mg) of nine (9) single-dose 500 mg vials
NDC and UPC	81960-031-03
WAC	Please contact your distributor
Minimum Quantity per Order	1 carton

HOW TO ORDER PEMGARDA

	CARDINAL HEALTH	CENCORA	MCKESSON PLASMA AND BIOLOGICS	MCKESSON SPECIALTY CARE DISTRIBUTION
Phone	855.855.0708	800.746.6273	877.625.2566	800.482.6700
Email	gmb-spd-csorderentry@cardinalhealth.com	service@asdhealthcare.com	mpborders@mckesson.com	physvcscustcare@mckesson.com
Portal	Specialty Online: specialtyonline.cardinalhealth.com Order Express: orderexpress.cardinalhealth.com	n/a	https://connect.mckesson.com/	https://mscs.mckesson.com/
Account Setup	866.677.4844	asdaccountsetup@amerisourcebergen.com	mpbonboarding@mckesson.com	onboarding2@mckesson.com

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, and infusion-related reactions occurring during the infusion and up to 24 hours after the infusion have been observed with PEMGARDA and may be severe or life threatening. If signs and symptoms of a clinically significant hypersensitivity reaction or infusion-related reaction occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals during infusion for at least two hours after infusion is complete.

Risk of Cross-Hypersensitivity With COVID-19 Vaccine

PEMGARDA contains polysorbate 80, which is in some COVID-19 vaccines and is structurally similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. For individuals with a history of severe hypersensitivity reaction to a COVID-19 vaccine, consider consultation with an allergist-immunologist prior to PEMGARDA administration.

Risk for COVID-19 Due to SARS-CoV-2 Viral Variants with Substantially Reduced Susceptibility to PEMGARDA

Certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA. PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. Inform individuals of the increased risk, compared to other variants, for COVID-19 due to SARS-CoV-2 viral variants that exhibit significantly reduced susceptibility to PEMGARDA. If signs and symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate.

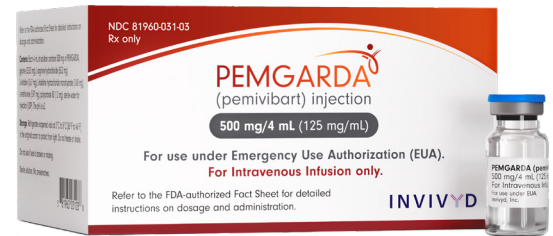
Please see additional Important Safety Information throughout and see the full [Fact Sheet for Healthcare Providers, including Boxed Warning](#) for more information on the EUA of PEMGARDA.

PEMGARDA™ PACKAGING INFORMATION

PEMGARDA is a sterile, preservative-free, clear to slightly opalescent, colorless to yellow solution supplied in single-dose vials intended for intravenous infusion only.

HOW SUPPLIED DESCRIPTION

Carton Dimensions (L x H x W) (in)	5.5 x 2.9 x 4.2
Carton Weight (lb)	0.44
Vials per Carton	9
Cartons per Case	24



PEMGARDA STORAGE AND HANDLING



Refrigerate unopened PEMGARDA vials at 2-8 °C (36-46 °F) in the original carton to protect from light.

Remove PEMGARDA vials from refrigerated storage and allow to equilibrate to room temperature (18-26 °C [64-79 °F]) for 10 minutes before preparation. **Do not expose to direct heat. Do not shake vials. Inspect the vials.**

If immediate administration is not possible, the diluted solution may be stored at room temperature under ambient light for up to 4 hours. Do not shake the diluted solution.

Please check the [FDA's Expiration Dating Extension](#) website for updates before administering or requesting a return of a product.

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse events (all grades, incidence $\geq 2\%$) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. PEMGARDA should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Lactation

There are no available data on the presence of PEMGARDA in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PEMGARDA and any potential adverse effects on the breastfed infant from PEMGARDA.

Pediatric Use

PEMGARDA is not authorized for use in pediatrics less than 12 years of age or weighing less than 40 kg. The safety and effectiveness of PEMGARDA has not been established in pediatrics.

Please see additional Important Safety Information throughout and see the full [Fact Sheet for Healthcare Providers, including Boxed Warning](#) for more information on the EUA of PEMGARDA.

IMPORTANT SAFETY INFORMATION (cont'd)

See full [Fact Sheet for Healthcare Providers](#) and [Fact Sheet for Patients, Parents, and Caregivers](#) for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. The [FDA Letter of Authorization](#) is also available for reference.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events* and medication errors potentially related to PEMGARDA™ within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500 (for information on how to access this form, see below). The FDA requires that such reports, using FDA Form 3500, include the following:

- Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, sex, weight, ethnicity, and race).
- A statement "PEMGARDA use for the pre-exposure prophylaxis of COVID-19 under Emergency Use Authorization (EUA)" under the "Describe Event, Problem, or Product Use/Medication Error" heading.
- Information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes).
- Patient's preexisting medical conditions and use of concomitant products.
- Information about the product (e.g., dosage, route of administration, NDC #).

Submit serious adverse event and medication error reports using FDA Form 3500 to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm.
- Complete and submit a postage-paid FDA Form 3500 (<https://www.fda.gov/media/76299/download>) and return by:
 - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
 - Fax to 1-800-FDA (332)-0178, or
- Call 1-800-FDA (332)-1088 to request a reporting form.

In addition, please provide a copy of all FDA MedWatch forms to:

Invivyd, Inc.

Email: pv@invivyd.com

Or call Invivyd, Inc. at 1-800-890-3385 to report serious adverse events.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about serious adverse events and medication errors following receipt of PEMGARDA.

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- Other important medical events, which may require a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

You may report side effects related to Invivyd, Inc. products by sending an email to medinfo@invivyd.com.

COVID-19, coronavirus disease 2019; FDA, US Food and Drug Administration; NDC, National Drug Code; UPC, Universal Product Code; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; WAC, wholesale acquisition cost.

Reference: PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc. 2024.

INVIVYD™, PEMGARDA™, and the Ribbon logos are trademarks of Invivyd, Inc.
©2024 Invivyd, Inc. All rights reserved. 222-NP-B-US-00004. Last updated 09/24.

