# Dosage, Administration, and Storage Guide

PEMGARDA
(pemivibart) injection
for intravenous use

## EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA™

PEMGARDA has not been approved, but has been authorized for emergency use by FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (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 immune response to COVID-19 vaccination.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

## 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.
- 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.

## 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.**

# DOSAGE, ADMINISTRATION, AND STORAGE GUIDE

PEMGARDA
(pemivibart) injection
for intravenous use

## DOSAGE FOR EMERGENCY USE

Each PEMGARDA™ carton contains a total dose (4500 mg) of nine (9) single-dose 500 mg vials.

### INITIAL DOSING

- The initial dosage of PEMGARDA in adults and adolescents (12 years of age and older weighing at least 40 kg) is **4500 mg** administered as a single intravenous (IV) infusion given over a minimum of 60 minutes.
- PEMGARDA should be administered by a qualified healthcare professional as an IV infusion diluted with **0.9% sodium chloride (normal saline)** for IV injection.

### REPEAT DOSING

- The repeat dosage of PEMGARDA is **4500 mg** administered as a single IV infusion over a minimum of 60 minutes given every 3 months.
- Repeat dosing should be timed from the date of the most recent PEMGARDA dose.
- PEMGARDA should be administered by a qualified healthcare professional as an IV infusion diluted with **0.9% sodium chloride (normal saline)** for IV injection.

**Please see the DOSAGE AND ADMINISTRATION section in the Fact Sheet for Healthcare Providers for complete instructions.**

- PEMGARDA should only be administered in settings in which healthcare providers have immediate access to medications to treat a severe hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS) as necessary.
- **No dosage adjustment** is recommended in pregnant or lactating individuals, in geriatrics, or in individuals with renal or hepatic impairment.
- In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered **at least 2 weeks after vaccination.**

## IMPORTANT SAFETY INFORMATION (cont'd)

### WARNINGS AND PRECAUTIONS

**Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions**

Serious hypersensitivity reactions, including anaphylaxis, have been observed during infusion and up to 24 hours after administration of PEMGARDA. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals during the 60-minute infusion and for at least two hours after completion of the infusion.

**Risk of Cross-Hypersensitivity With COVID-19 Vaccines**

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 Not Neutralized by PEMGARDA**

Certain SARS-CoV-2 viral variants may emerge that are not neutralized by monoclonal antibodies such as 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 emergent SARS-CoV-2 viral variants not neutralized by PEMGARDA. If signs or symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate.

### ADVERSE REACTIONS

The most common adverse events (all grades, incidence ≥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.

**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.**

# DOSAGE, ADMINISTRATION, AND STORAGE GUIDE

PEMGARDA
(pemivibart) injection
for intravenous use

## DOSE PREPARATION AND ADMINISTRATION

### MATERIALS NEEDED

- 9 single-dose vials of PEMGARDA™ (125 mg/mL)
- 50-mL prefilled bag of 0.9% sodium chloride (normal saline) for IV injection
- IV extension set with inline 0.2-micron filter
- Infusion pump or gravity infusion set
- 0.9% sodium chloride injection for flushing

### PREPARATION

1. 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.**
2. Remove and discard 36 mL from a 50-mL prefilled 0.9% sodium chloride IV bag.
3. Withdraw 36 mL of PEMGARDA from nine (9) vials into a polypropylene syringe(s) (eg, one 40-mL syringe or two 20-mL syringes) and inject into prepared 0.9% sodium chloride IV bag.
4. The final product for administration will contain 50 mL: 36 mL of PEMGARDA and 14 mL of 0.9% sodium chloride.*

### ADMINISTRATION

1. PEMGARDA should only be administered in settings in which healthcare providers have immediate access to medications to treat a severe hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.
2. Attach infusion set including inline 0.2-micron filter to prepared IV bag, then prime the infusion set.
3. Administer the entire 50 mL infusion using infusion pump or gravity infusion set over a minimum of 60 minutes. Administer entire contents of prepared IV bag to avoid underdosing.
4. Once infusion is complete, flush line with 0.9% sodium chloride.
5. Clinically monitor patients during infusion and observe patients for at least 2 hours after infusion is complete. If signs or symptoms of an anaphylactic reaction occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy.

**Please see the DOSAGE AND ADMINISTRATION section in the Fact Sheet for Healthcare Providers for complete instructions.**

*PEMGARDA is preservative-free and should be administered immediately. If not immediately administered, the diluted solution may be stored at room temperature for up to 4 hours.

## IMPORTANT SAFETY INFORMATION (cont'd)

### USE IN SPECIFIC POPULATIONS (cont'd)

**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.

See full **Fact Sheet for Healthcare Providers, including Boxed Warning** 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.

**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
(pemivibart) injection
for intravenous use

## STORAGE AND HANDLING

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

Do not freeze or shake. Do not use if seal is broken or missing.

The diluted solution may be stored at room temperature under ambient light for up to 4 hours.

## IMPORTANT SAFETY INFORMATION (cont'd)

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; EUA, emergency use authorization; FDA, US Food and Drug Administration; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

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



INVIVYD