Dosage, Administration, and Storage Guide

PEMGARDA®
(pemivibart) injection
for intravenous use | 125 mg/mL

DOSAGE FOR EMERGENCY USE

Each PEMGARDA® carton contains a total dose (4500 mg) of 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 1 hour
  - Clinically monitor individuals during the infusion and for at least 2 hours after completion of the infusion

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
  - Clinically monitor individuals during the infusion and for at least 2 hours after completion of the infusion

- PEMGARDA should be administered by a qualified healthcare provider as an IV infusion diluted in a 50 mL bag of **0.9% sodium chloride (normal saline)** for IV injection
- **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**

For full dosing and administration instructions, please see the Fact Sheet for Healthcare Providers

Links to: https://www.invivyd.com/wp-content/uploads/HCP-Fact-Sheet.pdf

EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA®

PEMGARDA has been authorized by FDA for the emergency use described below. It 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 FD&C Act, 21 U.S.C. § 360bbb 3(b)(1), unless the authorization is terminated or revoked sooner.

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 use permanently if signs or symptoms of anaphylaxis or any severe systemic reaction are observed and initiate appropriate medications and/or supportive therapy.**

Please see additional Important Safety Information on pages 2 and 3.

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EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA®

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (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.

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GLOBAL - Links to: https://www.invivyd.com/wp-content/uploads/HCP-Fact-Sheet.pdf

GLOBAL - Links to: https://www.invivyd.com/wp- content/uploads/FDA-Letter-of-Authorization.pdf

Please see additional Important Safety Information on page 3.
Please see accompanying Fact Sheet for Healthcare Providers and FDA Letter of Authorization.

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IMPORTANT SAFETY INFORMATION

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

Serious hypersensitivity reactions, including anaphylaxis, and infusion-related reactions can occur during the infusion and up to 24 hours after the infusion of 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. Permanently discontinue PEMGARDA in individuals who experience signs or symptoms of anaphylaxis.

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.

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.

The most common adverse events (all grades, incidence ≥2% and greater than placebo, through Month 6) observed in participants who have moderate-to-severe immune compromise in Cohort A PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, viral infection, upper respiratory tract infection, influenza-like illness, urinary tract infection, fatigue, headache, sinusitis, nasopharyngitis, influenza and pneumonia.

The most common adverse events (all grades, incidence ≥2% and greater than placebo, through Month 6) observed in participants who do not have moderate-to-severe immune compromise in Cohort B treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, enterovirus infection, and viral upper respiratory tract infection.

PEMGARDA should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

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.

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. See Section 6.4 of the accompanying Fact Sheet for more information

Complete and submit the report online: www.fda.gov/medwatch/report.htm. See Section 6.4 of the Fact Sheet for additional mechanisms for reporting.

Links to: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program

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DOSAGE, ADMINISTRATION, AND STORAGE GUIDE

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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°C-26°C [64°F-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 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, 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.

STORAGE AND HANDLING

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

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

This product is **preservative free** and should be **administered immediately**.*

COVID-19, coronavirus disease 2019.
*If not immediately administered, the diluted solution may be stored at room temperature under ambient light for up to 4 hours.

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Links to: https://pemgarda.com/

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Visit PEMGARDA.com

Read the FDA Letter of Authorization

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