These Clinical Guidelines have been created using resources that were current as of the "Reviewed" date noted at the beginning of the document. Clinicians should refer to the manufacturer's Prescribing Information (or equivalent) for the most up-to-date information. While CarepathRx has published these Clinical Guidelines after a close review of available literature and a clinical review process, given the evolving nature and complexity of modern pharmaceutical products, CarepathRx does not and cannot warrant or guarantee that these Clinical Guidelines reflect the objectively best or highest standard of care at any given time.

Nothing within these Clinical Guidelines is intended to supersede or interfere with any individual clinician's decision-making or professional judgment with respect to either (1) prescribing or dispensing the drug or product in question or (2) the overall treatment plan for an individual patient.

# Pemivibart (Pemgarda) Clinical Guideline for Home Intravenous Therapy

**Section:** Clinical Guideline
**Compliance:** ACHC Infusion Pharmacy
**ACHC Standards:** N/A
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## I. BACKGROUND

The U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for Pemivibart (Pemgarda) for pre-exposure prophylaxis against COVID-19 in eligible adults and children aged 12 and older who weigh at least 40 kg. Pemivibart is intended for vulnerable and immunocompromised individuals who may not achieve sufficient immunity from COVID-19 vaccination or for whom vaccination is not recommended. It is not authorized for treatment, post-exposure prophylaxis, or as a replacement for vaccination.

The CANOPY trial, which supported the Emergency Use Authorization (EUA) for pemivibart, involved two primary cohort groups: Cohort A and B. Cohort A included participants with moderate-to-severe immune compromise. Participants in this cohort received pemivibart in a single-arm, open-label trial format, focusing on its safety and efficacy in individuals who are more vulnerable to severe COVID-19 outcomes. Cohort B consisted of participants without moderate-to-severe immune compromise. Participants were randomly assigned to receive either pemivibart or a placebo in a controlled trial setting.

Pemivibart is a monoclonal antibody that targets the spike protein of the SARS-CoV-2 virus, specifically its receptor binding domain. By binding to this area, it prevents the virus from attaching to the human ACE2 receptor, thus inhibiting infection and lowering the risk of severe disease. This makes it a valuable option for those with compromised immune systems who might not respond effectively to vaccines. The following outlines the procedures for servicing patients in need of outpatient pemivibart infusions.

## II. PATIENT ACCEPTANCE CRITERIA

A. The decision to administer a first dose in the home by a field nurse will be determined on a case-by-case basis and reviewed by nursing and pharmacy management. The following criteria will be evaluated:

1. Prescriber preference
2. Allergy profile
3. Age
4. Other relevant social and/or medical history

B. Physician orders for pemivibart must include:

1. Drug
2. Dose
3. Route of administration
4. Frequency of administration

5. Emergency medications per protocol
6. Orders for pre-medications
7. Line care protocol
8. Routine lab monitoring, if applicable

C. Onboarding information for **pre-exposure prophylaxis of COVID-19:**

1. EUA Criteria Confirmation: Verify that the patient meets the criteria for Emergency Use Authorization (EUA). Relevant medical conditions may include but are not limited to:

    a. Active treatment for solid tumor and hematologic malignancies
    b. Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
    c. Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
    d. Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy)
    e. Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome)
    f. Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
    g. Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

2. Insurance Verification: Confirm insurance coverage and inform patients about any co-payments related to treatment.

3. Demographic Information: Collect any necessary demographic details.

D. Prior to starting therapy, patients should be evaluated for timing of recent COVID-19 vaccination: Patients must wait at least two weeks after receiving a COVID-19 vaccine before becoming eligible to receive pemivibart.

E. Dispensing pharmacy treatment protocol for anaphylaxis will be instituted unless a more comprehensive patient-specific order is provided by physician. See Appendix A (Nursing CarepathRx policy on *Management of Allergic/Anaphylactic Reactions*).

## III. PHARMACOLOGY OVERVIEW

**Refer to the most updated EUA healthcare fact sheet for most up to date information**

A. Indications:

1. The U.S. Food and Drug Administration (FDA) has granted an Emergency Use Authorization (EUA) for the unapproved product, Pemgarda (pemivibart). This EUA allows pemivibart to be used for pre-exposure prophylaxis against coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years and older) weighing at least 40 kg.

2. This authorization applies to individuals who:

a. Are not currently infected with SARS-CoV-2 and have not had a known recent exposure to someone infected with SARS-CoV-2, and
b. Have moderate-to-severe immune compromise due to a medical condition or the use of immunosuppressive medications or treatments, making them unlikely to have an adequate response to COVID-19 vaccination.

B. Dosing:

1. Adults and adolescents (12 years of age and older weighing at least 40 kg)

a. Initial Dosing - 4500 mg administered as a single intravenous (IV) infusion.
b. Repeat Dose - 4500 mg of pemivibart administered as a single IV infusion every 3 months.

C. Dose Adjustment:

1. No dosage adjustments are recommended for pemivibart in geriatric or renally impaired patients. The impact of hepatic impairment on pemivibart's pharmacokinetics remains unknown, as no clinical trials have been conducted in this population.

D. Duration- Duration of therapy is dependent on patient response and adverse reactions.

E. Contraindications:

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

F. Warnings and Precautions:

1. **Anaphylaxis:** Anaphylaxis occurred in 4 out of 623 (0.6%) clinical trial participants, with no cases in Cohort B (healthy participants). Two cases of anaphylaxis defined as serious adverse events (SAEs) related to pemivibart were reported, both reactions occurring during the second IV infusion at Month 3. Additionally, two participants experienced anaphylaxis (per FDA adjudication) during the first IV infusion, but these cases were not classified as serious adverse events. All affected individuals had Pemivibart permanently discontinued. Administration should only occur in settings equipped to manage anaphylaxis, with patients monitored during and for at least two hours after the infusion. If anaphylaxis symptoms arise, the infusion must be stopped immediately, and permanent discontinuation of pemivibart is advised.

2. **Hypersensitivity and infusion-related reactions**: These can occur with pemivibart during and up to 24 hours after infusion, with potential severity. Symptoms include fever, difficulty breathing, chest pain, and various skin reactions. If significant reactions arise, the infusion should be stopped immediately, and treatment initiated. For mild reactions, consider slowing or stopping the infusion. Patients must be monitored during and for at least two hours after the infusion, as hypersensitivity reactions can also occur beyond 24 hours.

3. **Risk of Cross-Hypersensitivity With COVID-19 Vaccines:** Pemivibart contains polysorbate 80, similar to components in some COVID-19 vaccines. Individuals with a history of severe hypersensitivity reactions to these vaccines should consult an allergist before administration.

4. **Risk for COVID-19 Due to SARS-CoV-2 Viral Variants with Substantially Reduced Susceptibility to Pemivibart:** Certain SARS-CoV-2 variants may emerge with significantly reduced susceptibility to pemivibart, potentially making it ineffective at preventing COVID-19 caused by these variants. Individuals should be informed about the

increased risk associated with these variants. If COVID-19 symptoms occur, such as fever, cough, or difficulty breathing, individuals should test for the virus and seek medical attention, including appropriate treatment.

5. **Pregnancy and lactation:** No dosage adjustment is recommended in pregnant or lactating women. Pemivibart has not been studied in pregnant or lactating women. Pemivibart should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

G. Pharmacokinetics:

1. Absorption: After a single IV dose of pemivibart 4500 mg, the population pharmacokinetic model estimated a mean Cmax of 1750 mcg/mL.

2. Distribution: Based on a population pharmacokinetic analysis, the mean pemivibart total volume of distribution at steady state was 5.54 L (coefficient of variation, 17%).

3. Metabolism: As a humanized IgG1 lamda monoclonal antibody, pemivibart is expected to be degraded into small peptides and amino acids via catabolic pathways in a manner similar to endogenous IgG.

4. Elimination: Based on a population pharmacokinetic analysis, the median pemivibart t(1/2) was 44.8 days (range, 28.1 to 64.6 days).

H. Adverse Reactions:

1. Anaphylaxis occurred in 4 out of 623 (0.6%) clinical trial participants, with no cases in Cohort B (healthy participants). No post-marketing reports have been observed.

2. Systemic Infusion-Related Reactions and Hypersensitivity Reactions were reported in 7% (20/306) of clinical trial participants who had moderate-to-severe immune compromise. These were defined as reactions occurring within 24 hours of the first Pemivibart dose and included infusion-related reaction, infusion-related hypersensitivity, hypersensitivity, fatigue, headache, tachycardia, brain fog, dermatitis, diarrhea, myalgia, nausea, paresthesia, presyncope, and tremor. All reactions were mild or moderate, but two reactions were classified as anaphylaxis.

3. Local Infusion Site Reactions: In Cohort A, local infusion site reactions occurred in 2% (6 out of 306) of participants with moderate-to-severe immune compromise after either the first or second dose, while no reactions were observed in Cohort B. The local reactions included bruising, erythema, rash, and injection site reactions, all of which were mild and did not result in treatment discontinuation. Additionally, 5% (14 out of 306) of participants in Cohort A experienced infusion site issues such as infiltration, extravasation, or vein rupture.

4. Other common adverse events: upper respiratory tract infection (6%), viral infection (4%), influenza-like illness (3%), fatigue (3%), headache (2%), and nausea (2%).

I. Drug Interactions: No drug-drug interaction studies have been conducted for pemivibart. Since it is not renally excreted or metabolized by cytochrome P450 enzymes, it is unlikely to interact with other medications that are renally excreted or that affect these enzymes. Consult interaction database for patient specific assessment.

## IV. ADMINISTRATIVE GUIDELINES

A. Administration: IV infusions should be given immediately after reconstitution and dilution. Complete infusion within 4 hours of preparation per current USP Immediate-Use Guidelines.

B. Administer pemivibart using an infusion set with an in-line or add-on **0.2-micron low protein binding filter**.

C. Do not co-administer other IV products in the same infusion line as pemivibart.

## V. NURSING PROCEDURE

A. Supplies may include but are not limited to:

1. Alcohol Swabs
2. Gloves
3. Tape
4. IV access supplies as applicable

    a. Peripheral IV access supplies for patients requiring peripheral IV access
        1) IV start Kit
        2) Peripheral IV catheter (ex. 22 Gauge x1" and 24 Gauge x ¾")
        3) Extension set 8" with needless connector
    b. Port access supplies for patients with a port
        1) Port needle (ex. 22 Gauge x ¾ to 1" safe step)
        2) Needless connector
        3) Central line dressing change kit

5. IV Pole
6. IV administration set (flow regulator or gravity tubing) with in-line or add-on **0.22-micron Filter**
7. Syringes (50 mL) with needles (20 G x 1")
8. Sharps container

B. Prescription items: (examples below)

1. Pemivibart vials
2. 0.9% sodium chloride (50 mL) stock bag
3. 0.9% sodium chloride (50mL) post infusion flush bag here if applicable
4. Standard flushes per protocol

C. How Supplied:

Pemivibart is a clear to slightly opalescent, colorless to yellow solution and is provided in single-dose vials with a concentration of 125 mg/mL. Each carton contains nine vials, and each vial has an overfill to enable the withdrawal of 500 mg (4.0 mL) of the drug.

D. Storage and Handling: Refrigerate unopened vials at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to protect from light. Do not freeze or shake. Do not use it if the seal is broken or missing.

E. Compatibility: Compatible with 0.9% sodium chloride

F. Procedures:

1. Explain the reason for the visit and use of pemivibart.

2. Don gloves.

3. Assess for signs and symptoms of viral infection prior to establishing venous access and preparing medication. Notify the ordering physician and pharmacist if signs or symptoms are present.

4. Establish venous access prior to preparation of drug.

5. Counsel patients on warnings, precautions, and potential side effects including but not limited to anaphylaxis, infusions reactions, upper respiratory tract and viral infection, influenza-like illness, fatigue, headache, and nausea.

6. Provide the following documentation and review with the patient the Fact Sheet for Patients, Parents, and Caregivers - Emergency Use Authorization (EUA) of PEMGARDA (pemivibart) for Coronavirus Disease 2019 (COVID-19) (Appendix B).

7. Prepare Product:

    a. Remove pemivibart vials from refrigerated storage and allow to equilibrate to room temperature (18°C to 26°C [64°F to 79°F]) for 10 minutes before preparation. Do not expose to direct heat. Do not shake vials.
    b. Visually inspect the vials for particulate matter and discoloration. Discard the vial if the solution is cloudy, discolored, or if visible particles are observed.
    c. Prepare IV bag by removing and discarding 36 mL from a 50 mL bag of 0.9% sodium chloride for IV injection.
    d. Withdraw 36 mL of pemivibart from nine vials into 50 mL syringe and inject into prepared 0.9% sodium chloride IV bag.
    e. The final product for administration will contain 50 mL: 36 mL of pemivibart and 14 mL of 0.9% sodium chloride.

8. Infusion Rates: Infuse over 60 minutes. Use an infusion set with an in-line or add on **0.2-micron filter**.

9. Post infusion flush: After administration of pemivibart, flush the entire administration tubing with 0.9% Sodium Chloride Injection to ensure all the medication is administered. Spike the 50mL 0.9% Sodium Chloride Injection bag and administer the flush at the same rate as the infusion of pemivibart.

10. Post infusion monitoring: Monitor patient and vital signs periodically during the infusion and 2 hours after the infusion is complete.

## VI. CLINICAL MONITORING

A. Prior to therapy, confirm patient meets eligibility for EUA use per these requirements:

1. Patient is not currently infected with SARS-CoV-2 and has not had a known recent exposure to someone infected with SARS-CoV-2.

2. Patient has moderate-to-severe immune compromise due to a medical condition or the use of immunosuppressive medications or treatments, making them unlikely to have an adequate response to COVID-19 vaccination.

3. Confirm COVID-19 vaccination timing: If patient has received the COVID-19 vaccine, it has been at least 2 weeks since administration.

B. During therapy:

1. Reduced incidence of COVID-19 caused by SARS-CoV-2 to ensure continued efficacy and use.

2. Assessment of signs and symptoms of adverse effects

   a. Healthcare providers are required to report all serious adverse events and medication errors related to the drug within 7 days of becoming aware of the event, using FDA Form 3500. Reports must include patient demographics, a statement identifying the use of Pemivibart under Emergency Use Authorization (EUA), details about the event, the patient's preexisting conditions, and product information.

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

      1) Complete and submit the report online: http://www.fda.gov/medwatch/report.htm
      2) 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
      3) Fax to 1-800-FDA (332)-0178, or
      4) Call 1-800-FDA (332)-1088 to request a reporting form.

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

      1) Invivyd, Inc. Email: pv@invivyd.com; or
      2) Call Invivyd, Inc. 1-800-890-3385 to report serious adverse events.

**Please refer to the EUA healthcare fact sheet for the most up to date guidance on this medication.**

**REFERENCES:**

Pemgarda (Pemivibart) [fact sheet]. Waltham, MA: Invivyd, Inc; 2024/September 2024.

United States Pharmacopeia (USP). General Chapter, <797> Pharmaceutical Compounding—Sterile Preparations. (2023) USP-NF. Rockville, MD: United States Pharmacopeia. Accessed October 31, 2024.

# APPENDIX A: ANAPHYLAXIS KIT INTRUCTIONS

## Emergency Medication After Your Infusion

**Please call your pharmacy if you have any questions or concerns. In the event of an emergency, always call 911.**

**Your nurse will tell you when you need to use Emergency Medications.**
**The epinephrine dose will be noted on the Anaphylaxis Protocol included with your kit.**

Start with a clean work surface and clean hands.

**Open the supply bag labeled Anaphylaxis Kit Contents.**

**You will need:**

1. **Bag containing Pills** (2 Acetaminophen and 2 Diphenhydramine)
2. **Bag containing Alcohol Prep Pads**
3. **Bag labeled IM Epinephrine**

**All other contents will not be needed.**

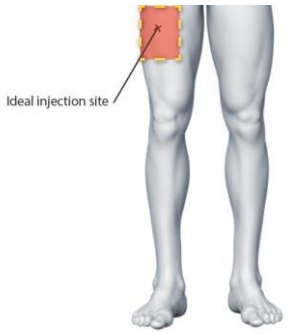
**Open the IM Epinephrine Bag**

1. **Remove 1 of each item**
    a. 1 -syringe
    b. 1 – brown labeled filter needle (BD Filter Needle)- **for ampule use only**
    c. 1 – black labeled safety needle (Magellan Hypodermic Safety Needle 22G x 1”)
    d. 1 ampule of epinephrine

**Prepare IM (intramuscular) injection of Epinephrine:**

1. **Attach the brown filtered needle to syringe**
    a. Be careful to not touch the tip of the syringe or the needle.
2. Using an **alcohol swab, wipe the neck of the epinephrine ampule.**
3. Holding the ampule upright, **swirl and flick the ampule until all fluid flows to the bottom chamber** (the top chamber should be empty).
4. Using a new alcohol wipe, grasp the neck of the ampule and with your other hand grasp the bottom chamber of the ampule. **Quickly snap the top of the ampule off, directing the snap way from you.**
5. **Place the tip of the brown filter needle inside the ampule**. Tilting the ampule, **withdraw dose of medication into the syringe** by gently pulling back on the plunger. Be careful to not pull the plunger out of the syringe.
6. Remove the needle from the ampule and h**old the syringe upright** with the needle pointing upward. **Gently tap the side of the syringe to bring any air to the top of the syringe.**
7. **Push the air out of the syringe by gently pushing on the plunger**.
8. Replace the cap on the brown filter needle. Discard remainder in ampule.
9. **Remove the brown filter needle and place the black safety needle onto the syringe.**

Give your IM Epinephrine injection




1. **Grasp your leg muscle at the outer mid-thigh** and **cleanse the area** with a new alcohol wipe.
2. **Push the needle into your leg muscle straight** in at a 90-degree angle.
3. **Inject the medication** by depressing the plunger in a slow and steady motion.
4. **Remove the needle** and wipe the site with the alcohol wipe.
5. May repeat dose every 5 minutes (**maximum 3 doses**) if ordered per protocol.

**Take the pills by mouth.**

a. 2 – Acetaminophen
b. 2 – Diphenhydramine

**Place all trash in the bag the pills came in** and take with you when you seek medical care. **Give the bag to the nurse or EMT**, so your doctor will know what medication you already took. They will properly dispose of the syringe and needles.
**Call 911** or have someone drive you to the emergency department.

# Appendix B: Fact Sheet for Patients, Parents, and Caregivers Emergency Use Authorization (EUA) of PEMGARDA (pemivibart) for Coronavirus Disease 2019 (COVID-19)

**What is the most important information I should know about PEMGARDA? PEMGARDA may cause serious side effects, including:**

- **A serious allergic reaction called anaphylaxis.** Anaphylaxis can be life- threatening and can happen during or after your infusion of PEMGARDA. In case you have a severe allergic reaction to PEMGARDA and need medical help right away, you will receive PEMGARDA in a healthcare setting. Your healthcare provider will monitor you for allergic reactions during your infusion and for at least 2 hours after you are finished receiving PEMGARDA. Your healthcare provider will stop PEMGARDA right away if you develop signs or symptoms of anaphylaxis or severe allergic reaction. **Tell your healthcare provider right away if you get any of the following signs or symptoms of anaphylaxis during or after your infusion of PEMGARDA:**
    - itching
    - flushing
    - hives
    - skin redness
    - swelling of your face, lips, mouth, tongue, throat, hands, or feet
    - sweating
    - dizziness
    - ringing in the ears
    - wheezing
    - trouble breathing
    - chest discomfort
    - fast heartbeat
- See "**What are the important possible side effects of PEMGARDA?**" for more information about side effects.

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you or your child with PEMGARDA for pre-exposure prophylaxis to help prevent coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus.

This Fact Sheet contains information to help you understand the potential risks and the potential benefits of receiving PEMGARDA, which you, or your child, have received or may receive.

The United States (US) Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make PEMGARDA available during the COVID-19 pandemic (for more details about an EUA please see **"What is an Emergency Use Authorization (EUA)?"** at the end of this document). PEMGARDA is not an FDA- approved medicine in the US.

Read this Fact Sheet for information about PEMGARDA. Talk to your healthcare provider about your options or if you have any questions. It is your choice for you or your child to receive PEMGARDA or stop at any time.

**What is COVID-19?**

COVID-19 is caused by a virus called a coronavirus (SARS-CoV-2). You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illnesses are mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like immune compromise, heart disease, lung disease, diabetes, and obesity, for example, seem to be at higher risk of being hospitalized for COVID-19.

**What is PEMGARDA?**

PEMGARDA is an investigational medicine that is used for pre-exposure prophylaxis to help prevent COVID-19 in adults and children 12 years of age and older who weigh at least 88 pounds (40 kg) who:

- are **not** currently infected with SARS-CoV-2 and who have **not** been known to be exposed to someone who is infected with SARS-CoV-2 **and**
- have moderate-to-severe immune compromise because of a medical condition or because they receive medicines or treatments that suppress the immune system **and** they are unlikely to have an adequate response to COVID-19 vaccination.

PEMGARDA is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PEMGARDA for prevention of COVID-19. The FDA has authorized the emergency use of PEMGARDA for pre- exposure prophylaxis to help prevent COVID-19 under an EUA. For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

PEMGARDA is **not** authorized:

- to treat COVID-19
- to prevent COVID-19 after being around someone infected with SARS-CoV-2 (post-exposure prophylaxis)
- when PEMGARDA is not expected to work against more than 90% of the SARS- CoV-2 variants in the US. Viruses can change over time (mutate) and develop into a slightly different form of the virus, called a variant.
- for use in children under 12 years of age or weighing less than 88 pounds (40 kg)

Pre-exposure prophylaxis to help prevent COVID-19 with PEMGARDA does not take the place of receiving COVID-19 vaccination in people who can be vaccinated for COVID-19. If your healthcare provider recommends it, you should receive a COVID-19 vaccination.

If you have received a COVID-19 vaccine, you should wait at least 2 weeks after vaccination to receive PEMGARDA.

**What should I tell my healthcare provider before I receive PEMGARDA?**

Tell your healthcare provider about all of your medical conditions, including if you:

- have any allergies, including if you have had a severe allergic reaction to a COVID-19 vaccine or to PEMGARDA.

- are pregnant or plan to become pregnant. It is not known if PEMGARDA can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if PEMGARDA can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive PEMGARDA.
- have any serious illnesses.
- take any medicines including prescription, over-the-counter, vitamins, and herbal products.

**How will I receive PEMGARDA?**

- You will receive 1 dose of PEMGARDA.
- PEMGARDA will be given to you through an infusion in a vein (intravenous [IV] infusion). It will take about 60 minutes to finish the infusion.
- You will receive PEMGARDA in a healthcare setting.
- You will be observed by a healthcare provider during your infusion and for at least 2 hours after your infusion is finished.

You may need to receive additional doses of PEMGARDA for ongoing protection from COVID-19. Viruses can change over time (mutate) and develop into a slightly different form of the virus, called a variant. Based on what we know about current SARS-CoV-2 variants, you may need to receive additional doses of PEMGARDA every 3 months.

**Who should generally not take PEMGARDA?**

Do not take PEMGARDA if you have had a severe allergic reaction to PEMGARDA or any ingredient in PEMGARDA. See the end of this Fact Sheet for a complete list of ingredients in PEMGARDA.

**What are the important possible side effects of PEMGARDA?**

- See **"What is the most important information I should know about PEMGARDA?"**
- **Allergic and infusion-related reactions.** Allergic and infusion-related reactions are common and can sometimes be severe or life-threatening. Allergic and infusion- related reactions can happen during and after your infusion of PEMGARDA. You may have an increased risk of allergic reaction with PEMGARDA if you have had a severe allergic reaction to a COVID-19 vaccine. PEMGARDA contains polysorbate 80, an ingredient in some COVID-19 vaccines. Also, polysorbate 80 is similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. Your healthcare provider may consult with a healthcare provider who specializes in allergy and immunology before giving you PEMGARDA if you have had a serious allergic reaction to a COVID-19 vaccine. Your healthcare provider will monitor you for allergic reactions during the infusion and for at least 2 hours after you receive PEMGARDA. **Tell your healthcare provider right away if you get any of the following signs or symptoms of an allergic or infusion-related reaction during or after your infusion of PEMGARDA:**

- fever
- trouble breathing or shortness of breath
- chills
- tiredness
- fast or slow heart rate
- chest pain or discomfort
- weakness
- confusion
- nausea
- headache
- throat tightness or irritation
- high or low blood pressure
- swelling of your face, lips, mouth, tongue, throat, hands, or feet
- rash, including hives
- itching
- muscle aches
- feeling lightheaded, faint, or dizzy
- sweating

The side effects of receiving any medicine by vein (IV) may include pain, redness, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

**The most common side effects in people treated with PEMGARDA** who have moderate-to-severe immune compromise include allergic and infusion-related reactions, infusion site reactions, common cold, viral infection, flu-like illness, tiredness, headache and nausea.

These are not all the possible side effects of PEMGARDA. Not a lot of people have been given PEMGARDA. Serious and unexpected side effects may happen.
PEMGARDA is still being studied, so it is possible that all of the risks are not known at this time.

**What other important information do I need to know when receiving PEMGARDA?**

**Risk of COVID-19 caused by certain SARS-CoV-2 variants:** Viruses can change over time (mutate) and develop into a slightly different form of the virus, called a variant.
PEMGARDA may not prevent COVID-19 caused by certain SARS-CoV-2 variants. If you are exposed to these variants, your chance of developing COVID-19 is higher than from other variants. Tell your healthcare provider right away, and test for COVID-19, if you develop any symptoms of COVID-19, including:

- fever or chills
- cough
- shortness of breath or difficulty breathing
- congestion or runny nose
- nausea or vomiting
- diarrhea
- headache
- sore throat
- new loss of taste or smell
- feeling tired (fatigue)
- muscle or body aches

For more information about the symptoms of COVID-19, go to https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.
If you develop COVID-19, your healthcare provider may recommend one of the available COVID-19 treatments.

**What other prevention choices are there?**

Vaccines to help prevent COVID-19 are approved or available under Emergency Use Authorization. Use of PEMGARDA does not replace vaccination against COVID-19. For more information about other medicines authorized for treatment or prevention of COVID-19, go to https://www.fda.gov/emergency-preparedness-and-response/mcm- legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

It is your choice to receive or not receive PEMGARDA for pre-exposure prophylaxis to help prevent COVID-19. Should you decide not to receive PEMGARDA, it will not change your standard medical care.

PEMGARDA is not authorized to treat COVID-19 or for post-exposure prophylaxis of COVID-19.

**What if I am pregnant or breastfeeding?**

There is no experience using PEMGARDA in women who are pregnant or breastfeeding. For a mother and unborn baby, the benefit of receiving PEMGARDA may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

**How do I report side effects with PEMGARDA?**

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away. Report side effects to FDA MedWatch at www.fda.gov/medwatch, or call 1-800-FDA-1088, or call Invivyd at 1-800-890-3385.

**How can I learn more about PEMGARDA?**

If you have questions, visit the website, or call the telephone number provided below. To access the most recent PEMGARDA Fact Sheet, please scan the QR code provided below.

| Website | Telephone Number |
|---|---|
| www.Pemgarda.com | 1-800-890-3385 |

**How can I learn more about COVID-19?**

- Ask your healthcare provider.
- Visit https://www.cdc.gov/COVID19.
- Contact your local or state public health department

**What is an Emergency Use Authorization?**

The United States FDA has made PEMGARDA available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Services (HHS) declaration under the Federal Food, Drug, and Cosmetic Act that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

PEMGARDA for pre-exposure prophylaxis to help prevent COVID-19 has not undergone the same type of review as an FDA-approved product. In issuing an EUA the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, it is reasonable to believe that the product may be effective for preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved, and available alternatives.

All these criteria must be met to allow the product to be used during the COVID-19 pandemic. The EUA for PEMGARDA is in effect for the duration of the COVID-19 HHS declaration justifying emergency use of PEMGARDA, unless terminated or revoked (after which PEMGARDA may no longer be used under the EUA).

**What are the ingredients in PEMGARDA? Active ingredient:**

pemivibart

**Inactive ingredients:** glycine, L-arginine hydrochloride, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, polysorbate 80, and sterile water for injection.

INVIVYD

Manufactured and distributed by**:** Invivyd, Inc., 1601 Trapelo Road, Suite 178, Waltham, MA 02451

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