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 authorized for use 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)
- 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
    - headache
    - throat tightness or irritation

- chills
- tiredness
- fast or slow heart rate
- chest pain or discomfort
- weakness
- confusion
- nausea
- 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 be effective at preventing 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

information on clinical studies of PEMGARDA and other therapies for the pre-exposure prophylaxis of COVID-19, see www.clinicaltrials.gov.

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 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 under the relevant COVID-19 declaration, 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 diagnosing, treating, or preventing COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or 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 of 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 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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