

<p>Patient Information</p> <p>CYFENDUS™ (Anthrax Vaccine Adsorbed, Adjuvanted) Suspension for Intramuscular Injection</p>
<p>Please read this Patient Information summary carefully before you get this vaccine. This summary does not take the place of talking with your healthcare provider about CYFENDUS. If you have questions or would like more information, please talk with your healthcare provider.</p>
<p>What is CYFENDUS?</p> <ul style="list-style-type: none"> • CYFENDUS is a vaccine licensed by the FDA to protect against anthrax disease when given with recommended antibacterial drugs in persons 18 through 65 years of age <u>after</u> exposure to anthrax. • CYFENDUS may not protect all vaccine recipients from anthrax disease. • How well CYFENDUS works when given after exposure to anthrax has been studied only in animals. It has not been studied in humans because there are not enough people who get the disease naturally, and it is not ethical to expose people to anthrax on purpose to find out how well CYFENDUS works. • The safety of CYFENDUS was studied in adults 18 through 65 years of age.
<p>Who should not get CYFENDUS?</p> <p>You should not get CYFENDUS if you have a history of severe allergic reaction to any ingredient of the vaccine, including aluminum hydroxide, benzethonium chloride, formaldehyde, or CPG 7909 or had a serious reaction after getting CYFENDUS or BioThrax® (Anthrax Vaccine Adsorbed) previously</p>
<p>What should I tell my healthcare provider before getting CYFENDUS?</p> <ul style="list-style-type: none"> • If you may be pregnant, plan to get pregnant soon, or are nursing a baby. • About medicines that you take, including over-the-counter medicines and supplements. • About immune problems you have, including steroid treatments and cancer treatments.
<p>What if I discover I was pregnant at the time I got CYFENDUS?</p> <ul style="list-style-type: none"> • Inform your healthcare provider
<p>How is CYFENDUS given?</p> <p>CYFENDUS is given as an injection in your muscle.</p> <p>After getting the first dose, you should come back for the second dose two weeks later. It is important that you get both doses.</p> <p>You are being given CYFENDUS because you may have been exposed to anthrax. It is important that you also take antibacterial drugs as recommended by your healthcare provider.</p>

What are the possible or reasonably likely side effects of CYFENDUS?

The most common side effects of CYFENDUS are:

- Pain/tenderness, warmth, hardness, itching, swelling, redness, and bruising at the injection site
- Problems moving the arm in which you received the vaccine
- Muscle aches
- Tiredness
- Headache
- Fever

Tell your healthcare provider about any side effects that concern you and ask about acceptable treatments for relief of side effects. There may be other side effects that are not listed here. Talk to your healthcare provider if you have questions or concerns about possible side effects.

You may report side effects to **FDA by calling 1-800-822-7967** or to the website www.vaers.hhs.gov. You may also report side effects directly to Emergent BioSolutions at 1-800-768-2304 or at medicalinformation@ebsi.com.

What are the ingredients in CYFENDUS?

CYFENDUS does not contain live bacteria. CYFENDUS contains bacterial proteins that are not alive and do not cause anthrax disease. CYFENDUS also contains aluminum hydroxide and CPG 7909 as adjuvants (substances added to some vaccines to enhance the immune response of vaccinated individuals), and benzethonium chloride and formaldehyde as preservatives.

Distributed by: Emergent Product Development Gaithersburg Inc.

Gaithersburg, MD USA 20879

License No. 2089