Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-006-CG
January 23, 2025

The FDA is warning about the risk of a rare but serious allergic reaction with the medicine glatiramer acetate (Copaxone, Glatopa), which is used to treat patients with multiple sclerosis (MS). This serious allergic reaction, called anaphylaxis, can occur at any time while on treatment, after the first dose or after doses administered months or years after starting the medicine. For most patients who experienced anaphylaxis with glatiramer acetate use, the symptoms appeared within one hour of injection. In some cases, anaphylaxis resulted in hospitalization and death.

RECOMMENDATIONS

1. **Patients and Caregivers**
   a. Patients should stop taking glatiramer acetate and seek immediate medical attention by going to an emergency room or calling 911 if you experience symptoms of an anaphylactic reaction.
      i. Symptoms generally appear within one hour of injection and include wheezing or difficulty breathing, swelling of the face, lips, or throat, and hives. These symptoms can quickly progress to more serious symptoms, including severe rash or shock, which is a life-threatening condition.
      ii. Anaphylaxis can occur at any point during glatiramer acetate treatment, including years after starting treatment.
      iii. You should not restart glatiramer acetate if you have experienced anaphylaxis unless another clear cause for anaphylaxis is identified.
      iv. Talk to your health care professional if you have any questions or concerns about glatiramer acetate.
   b. Patients should be aware that the early symptoms of anaphylaxis can be similar to a temporary reaction that sometimes happens right after or within minutes after an injection of the medicine into the skin.
      i. This immediate post-injection reaction goes away on its own, usually within 15-30 minutes, with no specific treatment. This reaction can

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occur with the first dose, or after doses administered months or even years after starting the medicine.

ii. This immediate post-injection reaction may involve symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives.

iii. Call the health care professional who prescribed the medicine if you have any of these immediate post-injection reaction symptoms.

iv. Do not continue taking more injections until your prescriber tells you to do so.

v. Seek immediate medical attention by going to an emergency room or calling 911 if any of these symptoms worsen or do not go away.

2. **Health Care Professionals**

a. Health care professionals should be aware that fatal anaphylaxis has occurred with glatiramer acetate, including years after treatment has been initiated and that the symptoms of these rare anaphylactic events may overlap with those of common immediate post-injection reactions.

i. Symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives typically occur within minutes after an injection and are generally transient, self-limited, and resolve without specific treatment within 30 minutes.

ii. Those associated with anaphylaxis are typically more severe, worsen, or last longer, requiring urgent medical attention.

b. Educate patients on the signs and symptoms of anaphylaxis and immediate post-injection reactions.

i. Instruct them to seek immediate medical attention by going to an emergency room or calling 911 if they experience any symptoms of anaphylaxis, and to contact their prescriber if they experience an immediate post-injection reaction.

ii. Do not restart the medicine in patients who experience anaphylaxis unless a clear alternative etiology is identified.

3. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

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Copaxone, Glatopa (glatiramer acetate): Drug Safety Communication - FDA Adds Boxed Warning About a Rare but Serious Allergic Reaction Called Anaphylaxis

Treat immediately if symptoms worsen or do not go away shortly after an injection

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[Posted 1/7/2025]

AUDIENCE: Patient, Caregiver, Health Care Professional, Pharmacy, Neurology

ISSUE: The FDA is warning about the risk of a rare but serious allergic reaction with the medicine glatiramer acetate (Copaxone, Glatopa), which is used to treat patients with multiple sclerosis (MS). This serious allergic reaction, called anaphylaxis, can occur at any time while on treatment, after the first dose or after doses administered months or years after starting the medicine. For most patients who experienced anaphylaxis with glatiramer acetate use, the symptoms appeared within one hour of injection. In some cases, anaphylaxis resulted in hospitalization and death.

The initial symptoms of anaphylaxis can overlap with those of a common reaction called immediate post-injection reaction that is temporary and can start soon after a shot is given. While immediate post-injection reaction is common, anaphylaxis is rare and its symptoms are typically more severe, worsen over time, and require treatment. Patients experiencing a reaction after the medicine is administered should seek immediate medical attention if the symptoms are more than mild, get worse over time, or do not go away within a brief time. FDA is adding a new Boxed Warning about this risk to the glatiramer acetate prescribing information and patient Medication Guide.

BACKGROUND: Glatiramer acetate is an FDA-approved medicine to treat patients with relapsing forms of MS. Glatiramer acetate is available as an injectable medicine administered daily or three times per week, depending on dosage, under the brand name Copaxone, branded generic name Glatopa, and as other generic glatiramer acetate products.

RECOMMENDATIONS:

Patients and Caregivers

- Patients should stop taking glatiramer acetate and seek immediate medical attention by going to an emergency room or calling 911 if you experience symptoms of an anaphylactic reaction.

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- Symptoms generally appear within one hour of injection and include wheezing or difficulty breathing, swelling of the face, lips, or throat, and hives. These symptoms can quickly progress to more serious symptoms, including severe rash or shock, which is a life-threatening condition.
- Anaphylaxis can occur at any point during glatiramer acetate treatment, including years after starting treatment.
- You should not restart glatiramer acetate if you have experienced anaphylaxis unless another clear cause for anaphylaxis is identified.
- Talk to your health care professional if you have any questions or concerns about glatiramer acetate.

- Patients should be aware that the early symptoms of anaphylaxis can be similar to a temporary reaction that sometimes happens right after or within minutes after an injection of the medicine into the skin.
  - This immediate post-injection reaction goes away on its own, usually within 15-30 minutes, with no specific treatment. This reaction can occur with the first dose, or after doses administered months or even years after starting the medicine.
  - This immediate post-injection reaction may involve symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives.
  - Call the health care professional who prescribed the medicine if you have any of these immediate post-injection reaction symptoms.
  - Do not continue taking more injections until your prescriber tells you to do so.
  - Seek immediate medical attention by going to an emergency room or calling 911 if any of these symptoms worsen or do not go away.

Health Care Professionals

- Health care professionals should be aware that fatal anaphylaxis has occurred with glatiramer acetate, including years after treatment has been initiated and that the symptoms of these rare anaphylactic events may overlap with those of common immediate post-injection reactions.
  - Symptoms such as flushing, chest pain, palpitations, anxiety, shortness of breath, rash, or hives typically occur within minutes after an injection and are generally transient, self-limited, and resolve without specific treatment within 30 minutes.
  - Those associated with anaphylaxis are typically more severe, worsen, or last longer, requiring urgent medical attention.

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- Educate patients on the signs and symptoms of anaphylaxis and immediate post-injection reactions.
  - Instruct them to seek immediate medical attention by going to an emergency room or calling 911 if they experience any symptoms of anaphylaxis, and to contact their prescriber if they experience an immediate post-injection reaction.
  - Do not restart the medicine in patients who experience anaphylaxis unless a clear alternative etiology is identified.

Health care professionals, patients and caregivers are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and **submit the report online.**
- **Download form** or call **1-800-332-1088** to request a reporting form, then complete and return to the address on form, or submit by fax to **1-800-FDA-0178.**

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