COMMUNICATION

COM-2025-003

23 JANUARY 2025

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

1/22/2025

Drug Indication:

For the treatment of Multiple Sclerosis (MS)

Safety Topic:

FDA adds a Boxed Warning about a rare but serious allergic reaction called anaphylaxis with the multiple sclerosis medicine known as glatiramer acetate (Copaxone™, Glatopa™)

FDA Adds Boxed Warning for Multiple Sclerosis Drugs Glatiramer Acetate (Copaxone™ and Glatopa™)

It is for this reason that we are notifying you that on 1/22/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Glatiramer Acetate (Copaxone, Glatopa).

Reason for Communication:

The FDA has released a Drug Safety Communication and added a boxed warning to the prescribing information about the risk of a rare but serious allergic reaction to Teva's Copaxone (glatiramer acetate) and its generic, marketed as Glatopa.

The FDA identified 82 worldwide cases of anaphylaxis associated with glatiramer acetate occurring from December 1996 through May 2024, including 19 cases that reported anaphylaxis more than one year after starting the medicine.

Pharmacy Required Action

Advise 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.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. U.S. Food and Drug Administration (2025). *FDA adds Boxed Warning about a rare but serious allergic reaction called anaphylaxis with the multiple sclerosis medicine glatiramer acetate (Copaxone, Glatopa).* https://www.fda.gov/drugs/drug-safety-and-availability/fda-adds-boxed-warning-about-rare-serious-allergic-reaction-called-anaphylaxis-multiple-sclerosis

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FRM-CL-000127-001

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