The Medical Letter®

on Drugs and Therapeutics

Volume 67 February 17, 2025

ISSUE No. 1722

IN THIS ISSUE

The Medical Letter®
on Drugs and Therapeutics

Volume 67 (Issue 1722) February 17, 2025

Take CME Exams

IN BRIEF

Anaphylaxis with Glatiramer Acetate

The FDA has required a new boxed warning in the label of the subcutaneously injected immunomodulatory drug glatiramer acetate (*Copaxone, Glatopa*, and generics) about a risk of anaphylaxis.[1] Glatiramer has been used for years to treat relapsing forms of multiple sclerosis (MS).[2]

A review of data from the FDA Adverse Event Reporting System and published case reports identified 82 cases of anaphylaxis associated with use of glatiramer acetate that occurred between December 1996 and May 2024, including 51 requiring hospitalization and 6 that were fatal. Most cases occurred within 12 months after starting treatment with glatiramer (one was a sudden death after the first dose), but about 25% of the cases occurred >12 months after the drug was started. Anaphylaxis typically occurred within 1 hour after injection.[1]

Glatiramer acetate and interferon beta (*Betaseron*, and others) are typically used to treat less active cases of relapsing MS; they are less effective than other disease-modifying drugs, but they cause less toxicity. Glatiramer is generally better tolerated than interferon and is similarly effective, but it must be injected more frequently.[2] Anaphylaxis has also occurred with use of interferon beta.

Patients receiving glatiramer acetate should be counseled about the risk of anaphylaxis and cautioned that symptoms of anaphylaxis can overlap with those of more typical injection-related reactions, such as flushing, shortness of breath, rash, and hives, which typically occur within minutes after injection and are generally self-limited.[1] ■

1. FDA Drug Safety Communication. FDA adds boxed warning about a rare but serious allergic reaction called anaphylaxis with the multiple sclerosis medicine glatiramer acetate (Copaxone, Glatopa). January 22, 2025. Available at: https://bit.ly/4jonnjN. Accessed January 23, 2025.
2. Drugs for multiple sclerosis. Med Lett Drugs Ther 2021; 63:42.

Subscription Services

Address:
The Medical Letter, Inc.
145 Huguenot St. Ste. 312
New Rochelle, NY 10801-7537
www.medicalletter.org

Customer Service:
Call: 800-211-2769 or 914-235-0500
Fax: 914-632-1733
E-mail: custserv@medicalletter.org

Permissions:
To reproduce any portion of this issue, please e-mail your request to:
permissions@medicalletter.org

Subscriptions (US):
1 year - $159; $65 per year for students, interns, residents, and fellows in the US and Canada.
Reprints - $45 per issue or article

Site License Inquiries:
E-mail: SubQuote@medicalletter.org
Call: 800-211-2769
Special rates available for bulk subscriptions.

Get Connected:

Copyright 2025. ISSN 1523-2859