Glatiramer acetate – Boxed warning added

- On January 22, 2025, the FDA announced that a ***Boxed Warning*** **for the risk of anaphylaxis will be added to the labels of all glatiramer acetate containing products (e.g., Copaxone®, Glatopa®)**.

- The FDA reviewed 82 serious cases of anaphylaxis worldwide associated with glatiramer acetate in the FAERS database and medical literature since the product was approved in December 1996 through May 2024. Of the 82 patients, 51 were hospitalized for anaphylaxis, including 13 who required care in the intensive care unit, and six died. Most of these reactions occurred within one hour of injection.

    - **The median time to onset of anaphylaxis from starting glatiramer acetate was 5 months**, ranging from one day to 72 months as follows: 12 patients within one month of starting the medicine, 48 patients between one and 12 months after starting, and 19 patients more than 12 months after starting it.
    - One patient case described shock and sudden death after the first dose, and the duration of treatment was not reported for three patients.
    - For context, there are more than 3 million patient-years of exposure to glatiramer acetate in the postmarket setting from 1996 through 2023.

- Glatiramer acetate is approved for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

- 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.

    - Patients should be educated on the signs and symptoms of anaphylaxis and immediate post-injection reactions. Patients should be instructed 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.