COPAXONE (Glatiramer Acetate) 20 mg/mL and 40 mg/mL – Long term anaphylactic reactions

Dear Healthcare Professional,

In agreement with Medsafe in New Zealand, Teva Pharma New Zealand Pty Ltd would like to inform you about anaphylactic reactions with Copaxone® (Glatiramer Acetate), that may occur months up to years after treatment initiation.

In summary:

- Anaphylactic reactions may occur shortly following administration of glatiramer acetate even months up to years after initiation of treatment. Cases with a fatal outcome have been reported.
- Advise patients and/or caregivers on the signs and symptoms of anaphylactic reactions and to seek immediate emergency medical care in the event of an anaphylactic reaction.
- If an anaphylactic reaction occurs, treatment with glatiramer acetate must be discontinued.

Please find below some background information on the safety concern as follows:

Glatiramer acetate is indicated for

- the reduction of the frequency of relapses in patients with Relapsing Remitting Multiple Sclerosis (RRMS).
- The treatment of patients with a single clinical event suggestive of multiple sclerosis and at least two clinically silent MRI lesions characteristic of multiple sclerosis (MS), if alternative diagnoses have been excluded.

Glatiramer acetate is approved for subcutaneous injection in 20 mg/ml solution (once daily injection) and 40 mg/ml solution (three times weekly and at least 48 hours apart injection).

Glatiramer acetate can cause post-injection reactions as well as anaphylactic reactions.

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Following an EU-wide review of all available data concerning anaphylactic reactions with glatiramer acetate, it has been concluded that the medicine is associated with anaphylactic reactions which may occur shortly following administration of glatiramer acetate even months up to years after initiation of treatment. Cases with a fatal outcome have been reported.

Anaphylactic reactions are reported uncommonly (⩾1/1,000 to <1/100) with glatiramer acetate 20 mg/ml and glatiramer acetate 40 mg/ml solution for injection.

Patients receiving treatment with glatiramer acetate and their caregivers should be informed about the signs and symptoms of anaphylactic reactions, and instructed to seek immediate emergency medical care if an anaphylactic reaction occurs. This is particularly important given the seriousness of anaphylactic reactions and the possibility for self-administration in the home setting. Moreover, some of the signs and symptoms of an anaphylactic reaction may overlap with post-injection reactions, leading to a potential delay in the identification of an anaphylactic reaction.

The product information of all glatiramer acetate-containing medicines will be updated with new information regarding the risk of anaphylactic reactions, including anaphylactic reactions occurring months up to years after initiation of treatment, and the new measures to be taken.

Please report any suspected adverse reactions/events associated with the use of glatiramer acetate to Medsafe/Centre for Adverse Reactions Monitoring at https://pophealth.my.site.com/carmreportnz/s/

and to below company contact point:

Teva drug safety reporting: Safety.Australia@tevapharm.com or
N.Z. Phone: 0800 800 097 (Option 1)

For further information, please contact Teva Pharma New Zealand Ltd via email:
MedInfo.ANZ@tevapharm.com

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Yours faithfully,

Dr. H.H. Teh

Medical Affairs Director

Teva Pharma Australia Pty. Ltd.

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