PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Direct Healthcare Professional Communication

14th August 2024

Glatiramer acetate: Anaphylactic reactions may occur months up to years after treatment initiation.

Dear Healthcare professional,

Teva Pharmaceuticals Ireland and Viatris Limited in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

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.**

Background on the safety concern

Glatiramer acetate is indicated for the treatment of relapsing forms of multiple sclerosis (MS). Glatiramer acetate is approved for subcutaneous injection in 20 mg/ml solution (once daily injection) and 40 mg/ml solution (three times weekly injection).

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

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.

Call for reporting:
Reporting suspected adverse reactions after authorisation of the medicinal products is important.It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Company contact point:
Suspected adverse reactions should also be reported to the relevant Marketing Authorisation Holders (see contact details below). This information is being provided jointly by the following MAHs:

Table 1

Marketing Authorisation Holder	**Medicinal Product Full Name**	**Marketing Authorisation Number**	**Email**	**Telephone**
TEVA Pharmaceuticals Ireland	Copaxone (Glatiramer acetate) 20 mg/ml solution for injection in pre-filled syringe	PA22579/001/001	Medical Enquiries: medinfo@tevauk.com Adverse Events: UK.safety@tevauk.com	+44 (0) 207 540 7117
	Copaxone (Glatiramer acetate) 40 mg/ml solution for injection in pre-filled syringe	PA22579/001/002		
Viatris Limited	Brabio (glatiramer acetate) 20 mg/ml solution for injection, pre-filled syringe	PA23266/010/001	Medical Enquiries: info.uk@viatris.com Adverse Events: pv.uk@viatris.com	Medical Enquiries: +44 (0) 1707 853 000 (option 1) Adverse Events: +44 (0) 1707 853 000 (option 1)
	Brabio (glatiramer acetate) 40 mg/ml solution for injection, pre-filled syringe	PA23266/011/001		

Yours faithfully,

Dr Makarand Bagul
Senior Medical and Technical Director, UK and Ireland
TEVA Pharmaceuticals Ireland

Signed on behalf of the Marketing Authorisation Holders Listed in the Table 1 above.