<Date>

Direct Healthcare Professional Communication (DHPC)

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

Dear Healthcare Professional,

The marketing authorisation holder, Teva Group, in agreement with the European Medicines Agency and <National Competent Authority> 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

Please report any suspected adverse reactions associated with the use of glatiramer acetate in accordance with the national requirements via the national spontaneous reporting system, to:

<details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system>.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>.

Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Glatiramer acetate
Marketing authorisation holder(s)	Teva Group, Viatris, Synthon, Zentiva *In cases where the DHPC concerns several marketing authorisation holders of the same active substance or is part of a class review, it is strongly encouraged that a single consistent message is sent to healthcare professionals in each EU Member State.* *All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single DHPC is prepared and circulated in each Member State. The letter circulated in each Member State should cover all active substance-containing products authorised in that Member State.* *It is encouraged that the originator marketing authorisation holder (where available) in each Member State acts as the contact point for the national competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no originator product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.*
Safety concern and purpose of the communication	Glatiramer acetate may cause anaphylactic reactions months or years after initiation of treatment. Initial symptoms of anaphylactic reactions may overlap with symptoms of post-injection reaction.
DHPC recipients	The target group should be further defined at national level, in agreement with the respective national competent authority. E.g. Neurologists, Neurologic departments, General Practitioners, Pharmacies, Emergency rooms/departments/doctors and other Healthcare professionals in contact with MS patients
Member States where the DHPC will be distributed	All EU/EEA Member States where glatiramer acetate is authorised.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	11 July 2024
DHPC and communication plan (in English) agreed by CMDh	24 Jul 2024
Submission of translated DHPCs to the national competent authorities for review	31 Jul 2024

Agreement of translations by national competent authorities	07 Aug 2024
Dissemination of DHPC	14 Aug 2024