Viatris UK Limited
Building 4
Trident Place,
Mosquito Way
Hatfield,
AL10 9UL

19th April 2023

Dear Healthcare Professional,

Summary: Patient information leaflet update for Brabio®(glatiramer acetate) 20 mg/ml solution for injection, pre-filled syringe, once daily dosage

Viatris*, the Marketing Authorization Holder of Brabio® (glatiramer acetate) 20mg/ml solution for injection in the UK, would like to inform you about a change to the patient information leaflet (PIL).

In order to prevent a delay in the supply of Brabio® (glatiramer acetate) Viatris has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to continue to supply packs which include the previous PIL, with copies of the updated PIL accompanying this letter.

The following information has been added to the new PIL. However, we would like to highlight that there has been no change to either the device or medicine.

Section 2. What you need to know before you use Brabio

Warnings and precautions

- If you have or have had any **liver problems** (including those due to alcohol consumption)

Section 4. Possible side effects

Liver problems

Liver problems or worsening of liver problems, including liver failure (some cases resulting in liver transplantation), can occur rarely with Brabio.

Contact your doctor right away if you have any symptoms, such as:

• nausea

• loss of appetite

• dark colored urine and pale stools

• yellowing of your skin or the white part of your eye

• bleeding more easily than normal

For patient information, we have attached a second letter communicating this change. Please could you pass the patient letter and up to date version of the PIL provided on to the patient and assess if the update will impact the patients currently established on Brabio.

If you have any questions about this letter, please contact Medical Information at the following address: **Medical Information**, Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, UK. Telephone: +44 (0)1707 853 000 or email info.uk@viatris.com

Product Indication

Glatiramer acetate is indicated for the treatment of relapsing forms of multiple sclerosis (MS).

Glatiramer acetate is not indicated in primary or secondary progressive MS.

Healthcare professionals should continue to consult the UK SPC.
A copy of the SPC can be accessed online on the electronic medicines compendium at https://www.medicines.org.uk/emc/product/8536/smpc#gref

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Suspected adverse drug reactions should also be reported to **Pharmacovigilance on +44 (0)1707 853 000** or email pv.uk@viatris.com

Yours faithfully,

Dr Ken Tam,
UK Medical Lead,
Viatris

** Generics [UK] Limited t/a Mylan is the Marketing Authorisation Holder, part of the Viatris group of companies.*