Preferred Product - Glatiramer acetate: BRABIO®

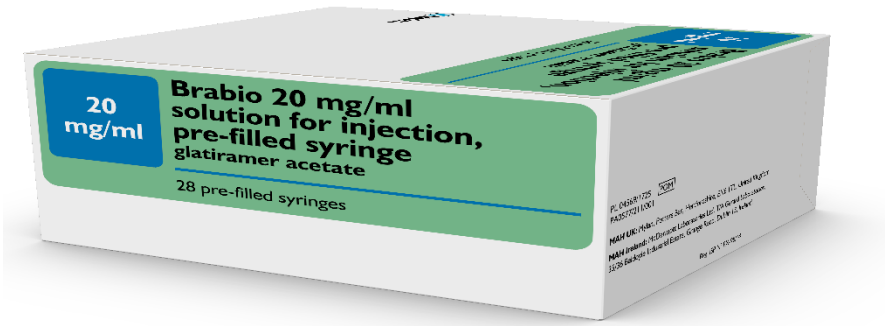
Information for Healthcare Professionals

The MMP recommends Brabio® as the preferred product for glatiramer acetate. Prescribing Brabio® will lead to significant savings for the health service, in the order of millions of euros.

Brabio® solution for injection in pre-filled syringe (PFS) is available in the following strengths on the High Tech Arrangement:

- 20 mg/ml
- 40 mg/ml

Brabio® 20 mg/ml pre-filled syringe



- Each pack contains 28 PFS, each containing 20 mg of glatiramer acetate in 1 ml, equivalent to 18 mg of glatiramer.
- No latex is used in the product or packaging; Brabio® 20 mg/ml PFS is therefore suitable for use in patients with a latex allergy.
- It is supplied as a clear, colourless to slightly yellow/brownish solution, free from visible particles.

Storage

- Brabio® 20 mg/ml PFS should be stored in a refrigerator (2°C - 8°C). It should not be frozen.
- The PFS should be kept in the original packaging in order to protect it from light.
- If the PFS cannot be stored in the refrigerator, then they can be stored between 15°C and 25°C, once, for up to one month. After this one-month period, if the PFS have not been used and are still in their original packaging, they must be returned to storage in a refrigerator (2°C - 8°C).

Dose Administration

- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFS.

- There is no safety feature upon delivery of the dose of glatiramer acetate; the needle does not retract within the sleeve.
- Alternatively, a reusable autoinjector device is available for use with Brabio® 20 mg/ml PFS, the MyJECT device.
- The MyJECT device allows the patient to adjust the needle length and therefore, the needle depth for administration.
- Delivery of the dose of glatiramer acetate via the MyJECT device commences when the patient presses the white injection button. The patient will hear the first click as delivery of the dose starts.
- The patient should continue to hold the device down against their skin until they hear the second click and they see the yellow checkmark in the viewing window. This confirms delivery of the dose of glatiramer acetate.
- Once the MyJECT device is removed from the skin, the PFS should be disposed of as outlined in the MyJECT instructions for use.
- The MyJECT device is supplied via the Brabio®, IQVIA patient support nurse service. The Brabio patient support programme employs registered nurses to guide Brabio® patients on how to use and administer their medication, utilising the MyJECT device. In addition, each MyJECT device comes with its own instructions for use manual.

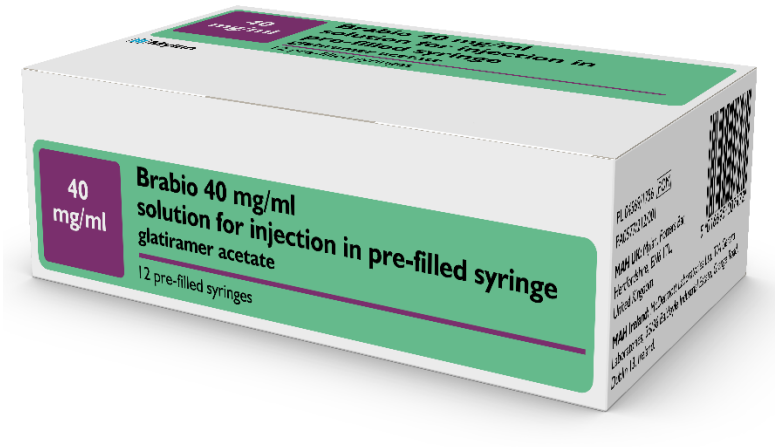
Similarities between Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS

- Both Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS contain the same excipients i.e. mannitol, water for injections.
- The solution for injection in both Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS has a pH of 5.5-7.0 and an osmolarity of about 265 mOsmol/L.
- Both Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS have a shelf life of three years.
- The recommended dosage for Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS is the same i.e. 20 mg of glatiramer acetate (one PFS) administered as a subcutaneous injection once daily.
- The manufacturers of both Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS provide autoinjector devices for use with the PFS presentations.
- Both autoinjector devices require the patient to press an activator button in order to deliver the dose of glatiramer acetate from Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS.
- When using the autoinjector devices for Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS, an initial click signals the start of the injection. When the injection is complete, a second click will be heard and the indicator window display will change to confirm the delivery of the dose of glatiramer acetate.

Differences between Brabio® 20 mg/ml PFS and Copaxone® 20 mg/ml PFS

- Brabio® 20 mg/ml PFS contains a clear, colourless to slightly yellow/brownish solution that is free from visible particles. Copaxone® 20 mg/ml PFS contains a clear solution, free of visible particles.

Brabio® 40 mg/ml pre-filled syringe



- Each pack contains 12 PFS, each containing 40 mg of glatiramer acetate in 1 ml, equivalent to 36 mg of glatiramer.
- No latex is used in the product or packaging; Brabio® 40 mg/ml PFS is therefore suitable for use in patients with a latex allergy.
- It is supplied as a clear, colourless to slightly yellow/brownish solution, free from visible particles.

Storage

- Brabio® 40 mg/ml PFS should be stored in a refrigerator (2°C - 8°C). It should not be frozen.
- The PFS should be kept in the original packaging in order to protect it from light.
- If the PFS cannot be stored in the refrigerator, then they can be stored between 15°C and 25°C, once, for up to one month. After this one-month period, if the PFS have not been used and are still in their original packaging, they must be returned to storage in a refrigerator (2°C - 8°C).

Dose Administration

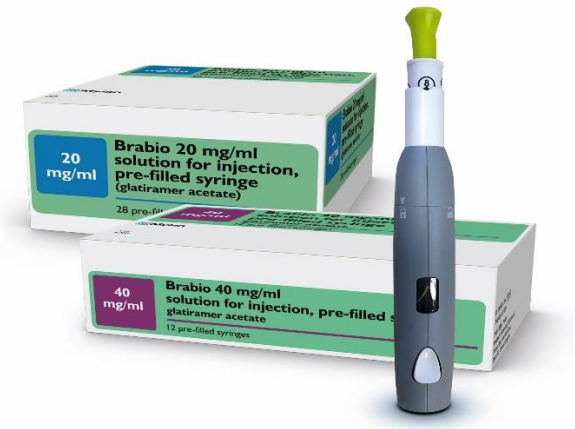
- The patient information leaflet contains a very clear diagrammatic guide on how to administer a dose from the PFS.
- There is no safety feature upon delivery of the dose of glatiramer acetate; the needle does not retract within the sleeve.
- Alternatively, a reusable autoinjector device is available for use with Brabio® 40 mg/ml PFS, the MyJECT device.
- The MyJECT device allows the patient to adjust the needle length and therefore, the needle depth for administration.
- Delivery of the dose of glatiramer acetate via the MyJECT device commences when the patient presses the white injection button. The patient will hear the first click as delivery of the dose starts.
- The patient should continue to hold the device down against their skin until they hear the second click and they see the yellow checkmark in the viewing window. This confirms delivery of the dose of glatiramer acetate.
- Once the MyJECT device is removed from the skin, the PFS should be disposed of as outlined in the MyJECT instructions for use.
- The MyJECT device is supplied via the Brabio®, IQVIA patient support nurse service. The Brabio patient support programme employs registered nurses to guide Brabio® patients on how to use and administer their medication, utilising the MyJECT device. In addition, each MyJECT device comes with its own instructions for use manual.

Similarities between Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS

- Both Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS contain the same excipients i.e. mannitol, water for injections.
- The solution for injection in both Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS has a pH of 5.5-7.0 and an osmolarity of about 300 mOsmol/L.
- The recommended dosage for Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS is the same i.e. 40 mg of glatiramer acetate (one PFS) administered as a subcutaneous injection three times a week, with each injection at least 48 hours apart.
- The manufacturers of both Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS provide autoinjector devices for use with the PFS presentations.
- Both autoinjector devices require the patient to press an activator button in order to deliver the dose of glatiramer acetate from Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS.
- When using the autoinjector devices for Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS, an initial click signals the start of the injection. When the injection is complete, a second click will be heard and the indicator window display will change to confirm the delivery of the dose of glatiramer acetate.

Differences between Brabio® 40 mg/ml PFS and Copaxone® 40 mg/ml PFS

- Brabio® 40 mg/ml PFS has a shelf life of three years while Copaxone® 40 mg/ml PFS has a shelf life of two years.
- Brabio® 40 mg/ml PFS contains a clear, colourless to slightly yellow/brownish solution that is free from visible particles. Copaxone® 40 mg/ml PFS contains a clear solution, free of visible particles.



Brabio® 20 mg/ml and 40 mg/ml PFS and MyJECT device

Viatris Ireland Patient Support Service

Viatris Ireland provides a patient support service to patients who have been prescribed Brabio®. This is provided by IQVIA and Stericycle on behalf of Viatris Ireland.

The following services are available as part of the patient support service:

- Support with injection preparation from Brabio® nurse service
- Supervision of injection administration and education regarding rotation of injection site – this includes education on injection administration by nurses in the patient's home
- Post-home visit education report shared with the healthcare professional team
- Sharps management service
- Travelling with therapy – this includes information on how to manage Brabio® while travelling, the provision of a cooler bag and supply of a mini bin for sharps management
- Medication compliance and adherence – this includes phone calls or visits to the patient's home to review medication adherence to date, review injection technique and resolve any issues
- Text messaging service

In order to avail of the patient support services for patients who have been prescribed Brabio®, please contact IQVIA through the secure mailbox viatrispsp@iqvia.com or by calling +353 800 930952.

Training on the MyJECT device is available via the Brabio® IQVIA nurse service. To obtain patient or healthcare professional support materials for use in clinics, please contact the manufacturing authorisation holder of Brabio® on +353 1871 1600. For medical information queries, please contact info.uk@viatris.com.

References:

1. Brabio® 20 mg/ml solution for injection, pre-filled syringe. Summary of Product Characeteristics and Patient Information Leaflet. Last revised December 2020. Accessed at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA0577-211-001_06042020152840.pdf on 13/01/2021.
2. Brabio® 40 mg/ml solution for injection in pre-filled syringe. Summary of Product Characteristics and Patient Information Leaflet. Last revised June 2020. Accessed at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA0577-212-001_10072020151435.pdf on 13/01/2021.