To be completed by Affiliate : <Document reference number>
<Date>

BRIVIACT® (IN ITALY: NUBRIVEO®) (BRIVARACETAM 10MG/ML) ORAL SOLUTION: BOTTLES WITH NARROW NECK DIAMETER

Dear Pharmacists,

UCB <name of local affiliate> in agreement with the European Medicines Agency and the <National Competent Authority > would like to inform you of the following:

Summary

- **A small number of glass bottles from some batches of Briviact® 10mg/mL oral solution, 300 mL, have a slightly narrower neck diameter, making it difficult to insert the press-in bottle adapter (PIBA) to extract the solution with the oral syringe.**
- **Discuss this issue with the patient/caregiver when dispensing the product and, if possible, check with the patient/caregiver if the PIBA fits in the dispensed bottle. If the PIBA does not fit in the dispensed bottle and there are difficulties extracting the dose, a replacement bottle should be provided.**
- **The issue of narrow neck of the bottle does not impact the safety of the Briviact® oral solution itself. However, a minimal risk of dosing error due to the use of the defective bottle or to the use of the syringe without the PIBA, cannot be ruled out.**
- **UCB is working with glass bottle manufacturer to solve this issue. The potentially impacted batch numbers are provided below and per your country one or more of the batches may be applicable. There may be very few bottles affected in the distributed batches whose shelf-life is up to 2025. Therefore, complaints could be received until that timeline.**

Background information

Briviact® (in Italy: Nubriveo®) is indicated as adjunctive therapy in treatment of partial onset seizures with or without secondary generalisation in patients from 4 years of age with epilepsy.

A small number of glass bottles from following batches of Briviact® oral solution have a slightly narrower neck diameter, and the press-in bottle adapter (PIBA) included in the package therefore does not fit into these bottles. This makes it difficult to extract the dose

of the oral solution from the bottle using the oral syringe (as described in the product information leaflet).

Potentially impacted batches include batch number 296954, 299727, 299736, 299738, 299914, 300505, 301008, 301010, 301918, 302346, 302874, 302960, 302961, 303261, 304171, 304173, 304224, 305150, 305151, 305657, 305708, 306231, 306232, 306233, 306234, 306235, 306236, and 308284; per your country one or more of these may be applicable.

There may be very few bottles affected in the distributed batches whose shelf-life is up to 2025. Therefore, complaints could be received until that timeline.

The patient/caregiver should be informed of this issue when dispensing Briviact® 10mg/mL oral solution. If possible, fitting of the PIBA in the dispensed bottled should be verified with the patient/caregiver.

If the PIBA does not fit in the dispensed bottle and there are difficulties extracting the dose, a replacement bottle should be provided. UCB will reimburse the cost of this replacement.

Although the dosing syringes included with the Briviact® oral solution are not impacted, minimal risk of dosing errors cannot be ruled out due to this issue. However, the issue of narrow neck of the bottle does not impact the safety of the Briviact® oral solution itself.

Call for reporting

Patient safety is of utmost importance to UCB. This allows continuous monitoring of the benefit-risk balance of the medicinal product.

Please refer to the product information leaflet to report any side effects with the product.

UCB contact information

Should you have any questions, please contact UCB <name of local affiliate> Tel: <Telephone number>; Email: <Email id of local medical information>.

Yours sincerely,

<Title/signature>

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Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Briviact®, Nubriveo® (brivaracetam) 10mg/mL oral solution
Marketing authorisation holder(s)	UCB Pharma S.A.
Concern and purpose of the communication	Briviact® (in Italy: Nubriveo®) (brivaracetam 10mg/mL) oral solution: Bottles with narrow neck diameter
DHPC recipients	Pharmacists
Member States where the DHPC will be distributed	Belgium, Bulgaria, Denmark, Finland, Germany, Greece, Hungary, Italy, Luxembourg, Netherlands, Norway, Romania, Slovenia, Spain, Sweden and United Kingdom[1]

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	14 December 2020
Submission of translated DHPCs to the national competent authorities for review	3 working days after CHMP approval
Agreement of translations by national competent authorities	3 working days after submission to national competent authorities/local authority
Dissemination of DHPC	18 Dec 2020 or date provided by national competent authorities/local authority

[1] As of 1.2.2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period.