BRIVIACT®

SUMMARY OF RISK MANAGEMENT PLAN

Version 2.0

Active substance(s) (INN or common name):	Brivaracetam
Product(s) concerned (brand name(s)):	Briviact®
Marketing authorization holder:	UCB Pharma-AG
Version number :	2.0 (summary of EU RMP v8.1 , dated 10-Dec-2021)
Date of final sign off :	04-April-2023

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.
The RMP summary of Briviact® is a concise document and does not claim to be exhaustive.
As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.
Please note that the reference document which is valid and relevant for the effective and safe use of Briviact® in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. UCB-Pharma-AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Briviact®.

Date: 04 April 2023 20230404rmp summary-v2.0-pxl-ch

Contents

PART I: THE MEDICINE AND WHAT IT IS USED FOR

Pharmaceutical form(s) and strength(s)	Current: 10mg, 25mg, 50mg, 75mg, and 100mg film-coated tablets, 10mg/mL oral solution, or 10mg/mL solution for injection/infusion.
	Proposed: Not Applicable
Is/will the product be subject to additional monitoring in the EU?	No
Is/will the product be subject to additional monitoring in Switzerland ?	No

Brivaracetam is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in adults, adolescents, and children from 2 years of age with epilepsy (see SmPC for the full indication). It contains brivaracetam as the active substance, and it is given as oral tablet of the strengths 10mg, 25mg, 50mg, 75mg, and 100mg film-coated tablets; as 10mg/mL oral solution; or as 10mg/mL solution for injection/infusion.
Further information about the evaluation of Briviact's benefits can be found in its EPAR, including in its plain language summary, available on the European Medicines Agency website, under the medicine's webpage : Briviact (in Italy: Nubriveo) | European Medicines Agency (europa.eu)

PART II: RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERISE THE RISKS

Important risks of Briviact, together with measures to minimize such risks and the proposed studies for learning more about Briviact's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be as follows:

Specific information, such as warnings, precautions, and advice on correct use, in the Package Leaflet and SmPC addressed to patients and healthcare professionals. Additional details in the tables displaying the volume (according to the patient's body weight and dose) to be taken with the individual syringe included in the Package Insert Leaflet; color-coded syringes matching the pictograms displayed on the carton box; inclusion of clear and detailed instructions in the PIL. In the case of Briviact, routine risk minimization measures are considered sufficient to address the safety concerns of this medicinal product. Therefore, additional risk minimization measures are not considered necessary.

- Important advice on the medicine's packaging.
- The authorized pack size — the amount of medicine in a pack is chosen in a way to ensure that the medicine is used correctly.
- The medicine's legal status — the way a medicine is supplied to the patient (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Briviact is not yet available, it is listed under "missing information" in Table 2–1.

2.1 List of important risks and missing information

Important risks of Briviact are those that need special risk management activities to further investigate or minimize the risk so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Briviact. Potential risks are concerns for which an association with the use of this medicine is possible, based on available data, but such as association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (eg, on the long-term use of the medicine).

Table 2–1: List of important risks and missing information

Important identified risks	Suicidality (class label for anticonvulsant products)
Important potential risks	None
Missing information	Data during pregnancy and lactation
	Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, and cognitive and psychomotor development in pediatric patients

2.2 Summary of important risks

Table 2–2: Summary of important identified risks

Important identified risk: Suicidality (class label for anticonvulsant products)	
Evidence for linking the risk to the medicine	Suicide-related events have been reported more often in people who have epilepsy compared with the general population.
Risk factors and risk groups	Common additional disorders in patients with epilepsy that increase the risk of suicide include depression and learning difficulties or disability. A small increased risk of suicide-related events has also been reported in patients with epilepsy taking antiepileptic drugs including Briviact.
Risk minimization measures	Routine risk minimization measures: Available by prescription only Section 4.4, Special Warnings and Precautions for Use, of the Summary of Product Characteristics (SmPC; class wording) and Section 4.8, Undesirable Effects, of the SmPC Packaging: • The brivaracetam (BRV) oral tablet pack contains unit dose packaging (blister) that requires a sequential withdrawal of tablets, which could interfere with the accomplishment of suicidal thoughts. • Intravenous formulation is provided in vials containing BRV 50mg in total, and the administration will be performed by a healthcare professional and not the patient. • Oral solution is packaged in bottles with 300mL fill volumes with a concentration of BRV 10mg/mL. This corresponds to 3g of BRV if the entire volume is taken. Once placed, the adaptor for the 5 or 10mL oraldosing syringe is difficult to remove, thus limiting the ability to drink significant volume. The oral solution, although flavored, does not have a pleasant taste due to the bitter tasting drug substance. Additional risk minimization measures: None

Table 2–2: Summary of important identified risks

Missing information: Pregnancy and lactation	
Risk minimization measures	Routine risk minimization measures: Available by prescription only Section 4.6, Fertility, Pregnancy and Lactation, of the SmPC Additional risk minimization measures: None
Additional pharmacovigilance activities	Additional pharmacovigilance activities: • Participation in and sponsorship of European and International Registry of Antiepileptic Drugs in Pregnancy and North American Antiepileptic Drug Pregnancy Registry. Activities include provision of requested data from UCB to the registries and regular review of interim outputs from the registries. • The protocols include possible activities to follow-up the children.
Missing information: Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, and cognitive and psychomotor development in pediatric patients	
Risk minimization measures	Routine risk minimization measures: Available by prescription only Additional risk minimization measures: None

BRV=brivaracetam; SmPC=summary of product characteristics

.

2.3 Post-authorization development plan

2.3.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization of Briviact.

2.3.2 Other studies in post-authorization development plan

Additional pharmacovigilance activities include the following: European and International Registry of Antiepileptic Drugs in Pregnancy (EURAP) and North American AED Pregnancy Registry.
Purpose of the study: collect data on pregnancy. Prescribers and reporters of pregnancy cases are encouraged to register pregnant women exposed to AED into the EURAP and North American AED Pregnancy Registry. References to registries are included in the pregnancy follow-up letter, US Call Center script, and on information for Medical Science Liaisons.