



UCB to present new data at the American Epilepsy Society 75th Annual Meeting 2021 reinforcing long-standing commitment to advancing epilepsy treatment and care

- 17 scientific presentations illustrate and reinforce UCB's commitment to improving the lives of people living with epilepsy
- Scientific presentations provide additional insights into the efficacy and safety profile of BRIVIACT[®] (brivaracetam) and VIMPAT[®] (lacosamide) as well as insights into the early use of NAYZILAM[®] (midazolam) [FDA approved only]
- Insights into epilepsy management are provided by real-world studies focusing on a range of issues including the health burden of untreated epilepsy, treatment gaps for newly-diagnosed patients, the effects of antiseizure medication shortages, and cultural attitudes towards and experiences of epilepsy

Brussels (Belgium) & Atlanta, Georgia (USA) 3 December – 18:00 (CET): UCB today announced that new data from its epilepsy treatment portfolio (brivaracetam, lacosamide, levetiracetam, midazolam nasal spray) will be showcased at the 75th American Epilepsy Society Annual Meeting (Chicago, Illinois), 3-7 December 2021. Further insightful data on the management of epilepsy will also be presented, including the burden of untreated and treated epilepsy and research into health inequities.

“For approximately 30 years, we have provided options that have helped transform the treatment landscape and improved the lives of millions of people living with epilepsy, and we’re excited to present new data at this congress from our ongoing comprehensive research program,” said Charl van Zyl, Executive Vice President, Neurology & Head of Europe/International Markets at UCB. “We have a commitment to redefine the future of epilepsy medicine, and this congress is a special moment for us to connect with the community and healthcare professionals and share our ambitions.”

At the congress, UCB will be reporting data from several significant clinical and population health epilepsy studies. These data include the efficacy and tolerability of brivaracetam in children and adolescents with focal seizures, real-world evidence studies of brivaracetam in the United States, the long-term efficacy and tolerability of lacosamide for the treatment of Primary Generalized Tonic-Clonic Seizures (PGTCS) and the early use of midazolam nasal spray in patients with seizure clusters.

UCB will also host a scientific exhibit, "UCB, Leading with Science: From Established Therapies to New Approaches" on Sunday, 5 December, 08:00 - 11:00 ET, in McCormick Place West, Level 4, Room W474a, to provide attending healthcare professionals an opportunity to engage around UCB's epilepsy research, as well as to provide updates on clinical data and more information about clinical-studies recruiting.

Addressing health inequities in epilepsy management

Alongside scientific presentations, UCB will facilitate a satellite symposium exploring the cultural drivers in healthcare decision-making. In this session, thought leaders on the Hispanic experience of healthcare will share current thinking and research about how health professionals may optimize care delivery and address health inequities for Hispanic populations living with epilepsy. The symposium will cover Hispanic American culture and attitudes to healthcare, the impact of stigma, and implications for providers. The symposium – entitled "Addressing health inequities for over 700,000 people with epilepsy: improving the experience and outcomes for Hispanics in the U.S." - is hosted by Joseph Sirven, MD, professor of neurology and editor-in-chief of epilepsy.com, Mayo Clinic. Registered delegates can attend the symposium, 3 December, 18:00–20:00 ET, McCormick Place West Building (Room W190 A/B). The symposium will include an esteemed panel of speakers including: Lidia Moura, MD, MPH, assistant professor of neurology, Harvard Medical School, assistant in neurology, Massachusetts General Hospital; Jesus Eric Pina-Garza, MD, professor of neurology and pediatrics, director of pediatric epilepsy, the Children's Hospital at TriStar Centennial; Fabian Sandoval, MD, CEO & research director Emerson Clinical Research Institute. Inc.; Iris Loew-Friedrich, MD, PhD, executive vice president and chief medical officer, UCB; and Grant Simic, BMedSci CPHQ, executive population health partner, U.S. neurology, UCB.

Mike Davis, Head of U.S. Neurology at UCB, comments: "It is our ambition to tackle the everyday barriers people living with epilepsy face, including access to care. Hispanics are the single largest subpopulation of people living with epilepsy in the U.S., yet data shows that Hispanic patients are disproportionately impacted by cultural, socioeconomic, and language challenges that can impede access to care. UCB is helping to address these health inequities by providing culturally relevant resources on epilepsy and our medications, which can hopefully improve this gap in epilepsy care."

Poster presentations

The following is a guide to the UCB-sponsored poster presentations at the 75th American Epilepsy Society (AES 2021) Annual Meeting:

Brivaracetam Posters

- **Cognitive and Behavioral Effects and Tolerability of Adjunctive Brivaracetam in Children and Adolescents With Focal Seizures: Pooled, Interim Analysis.** Elshoff J-P, Fleyshman S, De La Loge C, Nondonfaz X, Reichel C, Floricel F, Smeyers P
- **Time Course of Treatment Emergent Adverse Events Potentially Associated With Behavioral Disorders During Adjunctive Brivaracetam Treatment of Adults With Focal Seizures.** Dimova S, Klein P, Laloyaux C, Nondonfaz X, Floricel F, Elmoufti S, Meador K
- **Real-world Study of Brivaracetam in the United States.** Dave H, French J, Altalib H, Henninger H, Porter R, Gelfand M, Martin M, Dongre P, Elmoufti S, Schulz A, Sperling M
- **Effectiveness and Tolerability of Brivaracetam by Reason for Initiation in Adults with Focal Seizures: Post Hoc Analysis of a Real-world, US Study.** Henninger H, Sperling MR, Altalib H, Dave H, Gelfand M, Porter R, Martin M, Elmoufti S, Schulz AL, Dongre P, French J

- **Patient-reported Outcomes in Mood, Fatigue, Sleep Disturbance, and Disability While on Brivaracetam Treatment: a Prospective Observational Study.** Altalib H, French J, Sperling M, Henninger H, Dave H, Gelfand M, Schulz A, Elmoufti A, Dongre P, Martin M

Lacosamide Posters

- **Long-term Efficacy and Tolerability of Adjunctive Lacosamide for the Treatment of Primary Generalized Tonic-clonic Seizures in Patients by Maximum Dose Used: Interim Post Hoc Analysis.** O'Brien TJ, Vossler DG, Farkas KM, Dimova S, Steiniger-Brach B, McClung C, Williams P, Roebing R, Watanabe M
- **Evaluating the Occurrence of Newly Diagnosed Health Conditions Among Neonates Exposed to Intravenous Lacosamide Using Real World Data.** Fong S, Kaur M, Utidjian L, Abend N, Dickinson K, Roebing R, Maltenfort M, Yuen N, Williams P, McDonald J, Kalilani L, McClung C, Foscett N, Forrest C [Please note that lacosamide is not approved for use in neonates by any regulatory authority worldwide. Please see footnotes for full indication]
- **Evaluating the Occurrence of Newly Diagnosed Health Conditions Among Pediatric Patients Exposed to Intravenous Lacosamide Using Real World Data.** Roebing R, Kaur M, Utidjian L, Dickinson K, Maltenfort M, Yuen N, Williams P, McDonald J, Kalilani L, McClung C, Foscett N, Forrest C
- **Neonatal Seizure Treatment Practices – A Multicenter US Study.** Utidjian L, Kaur M, Abend N, Dickinson K, Roebing R, Maltenfort M, Yuen N, Elmoufti S, McDonald J, McClung C, Foscett N, Forrest C [Please note that lacosamide is not approved for use in neonates by any regulatory authority worldwide. Please see footnotes for full indication]
- **Retrospective Study on Safety and Effectiveness of Lacosamide for Neonatal Seizures.** Kaur M, Utidjian L, Abend N, Roebing R, Dickinson K, Maltenfort M, Yuen N, Elmoufti S, McDonald J, McClung C, Foscett N, Forrest C [Please note that lacosamide is not approved for use in neonates by any regulatory authority worldwide. Please see footnotes for full indication]

Levetiracetam Posters

- **Antiseizure Medication Shortages are Associated with Increased Product Switching: an Analysis of Levetiracetam.** Welton J, Stratton G, Schoeninger B, Low MH, Moody A, D'Souza W

Midazolam nasal spray Posters [FDA approved only]

- **Early Intervention with Midazolam Nasal Spray and Efficacy in Patients With Seizure Clusters: Post-hoc Analysis of an Open-label Extension Trial.** Wheless JW, Brunnert M, Floricel F, Dimova S, Fannon B

General Epilepsy Posters

- **Health Burden of Untreated and Treated Epilepsy.** Chen Z, Ren T, Sharma S, Rychkova M, Dunne J, Lee J, Laloyaux C, Lawn N, Kwan P

- **Hispanic CARE (Cultural Attitudes Regarding Epilepsy): Patient, Caregiver, and Community Perspectives.** Simic G, Hansbrough K, Thompson J, Deegan C, Olabarrieta Y, Ennis A
- **Hispanic CARE (Cultural Attitudes Regarding Epilepsy): Health Care Stakeholder Perspectives.** Ennis A, Thompson J, Simic G
- **How Often Do Patients with a New Epilepsy Diagnosis Remain Untreated?** Decker B, Schriver E, Fischbein K, Smith D, Moyer J, Mowery D, Litt B, Ellis C, Hill C
- **Using Design Thinking to Reimagine the Community Pharmacist's Role in Epilepsy Care.** White HS, Zaraa S, Stergachis A, Simic G, Protos C, Ricafort L, Bacci JL

About Epilepsy¹⁻³

Epilepsy is a common neurological condition worldwide and affects approximately 50 million people.¹ Epilepsy and seizures can develop in any person at any age,² and is usually diagnosed after a person has had at least two seizures (or after one seizure with a high risk for more) that were not caused by some known medical condition.³

About UCB in Epilepsy

UCB has a rich heritage in epilepsy with over 20 years of experience in the research and development of antiepileptic drugs. As a company with a long-term commitment to epilepsy research, our goal is to address unmet medical needs. Our scientists are proud to contribute to advances in the understanding of epilepsy and its treatment. We partner and create super-networks with world-leading scientists and clinicians in academic institutions, pharmaceutical companies, and other organizations who share our goals. At UCB, we are inspired by patients, and driven by science in our commitment to support patients with epilepsy.

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8 000 people operating in more than 40 countries, the company generated revenue of € 5.3 billion in 2020. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

About BRIVIACT® (brivaracetam)

Important Safety Information about BRIVIACT® in the EU and EEA⁴

BRIVIACT® (brivaracetam) is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. **Contraindications** Hypersensitivity to the active substance, other pyrrolidone derivatives or any of the excipients. **Special warnings and precautions for use** Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic drugs (AEDs) in several indications, including BRIVIACT®. Patients should be monitored for signs of suicidal ideation and behaviour and appropriate treatment should be considered. Patients (and caregivers) should be advised to seek medical advice should any signs of suicidal ideation or behaviour emerge. BRIVIACT® film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take

BRIVIACT®. Brivaracetam film-coated tablets, solution for injection/infusion and oral solution contain less than 1 mmol sodium (23mg) per tablet/vial/ml respectively, that is to say essentially 'sodium free'. The oral solution contains 239.8 mg sorbitol (E420) in each ml. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product. The oral solution contains methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed). Brivaracetam oral solution contains propylene glycol (E1520). **Posology** No dose adjustment is needed in adults with impaired renal function. Based on data in adults, no dose adjustment is necessary neither in paediatric patients with impaired renal function. In adults with hepatic impairment, a 50 mg/day starting dose should be considered. In children and adolescents weighing 50 kg or greater, a 50 mg/day starting dose is recommended. A maximum daily dose of 150 mg administered in 2 divided doses is recommended for all stages of hepatic impairment. In children and adolescents weighing less than 50 kg, a 1 mg/kg/day starting dose is recommended. The maximum dose should not exceed 3 mg/kg/day. No clinical data are available in paediatric patients with hepatic impairment. **Interaction with other medicinal products and other forms of interaction.** With co-administration of BRIVIACT® 200 mg single dose and ethanol 0.6 g/L continuous infusion in healthy subjects there was no pharmacokinetic interaction, but the effect of alcohol on psychomotor function, attention and memory was doubled. Intake of BRIVIACT® with alcohol is not recommended. Limited clinical data are available implying that coadministration of cannabidiol may increase the plasma exposure of brivaracetam, possibly through CYP2C19 inhibition, but the clinical relevance is uncertain. In healthy subjects, co-administration with rifampicin, a strong enzyme-inducer (600 mg/day for 5 days), decreased BRIVIACT® area under the plasma concentration curve (AUC) by 45%. Prescribers should consider adjusting the dose of BRIVIACT® for patients starting or ending treatment with rifampicin. Other strong enzyme-inducers (such as St John's wort [*Hypericum perforatum*]) may also decrease the systemic exposure of BRIVIACT®. Therefore, starting or ending treatment with St John's wort should be done with caution. *In vitro* studies have shown that brivaracetam exhibits little or no inhibition of CYP450 isoforms except for CYP2C19. Brivaracetam may increase plasma concentrations of medicinal products metabolised by CYP2C19 (e.g., lansoprazole, omeprazole, diazepam). CYP2B6 induction has not been investigated in vivo and BRIVIACT® may decrease plasma concentrations of medicinal products metabolised by CYP2B6 (e.g. efavirenz). *In vitro* studies have also shown that BRIVIACT® has inhibitory effects on OAT3. BRIVIACT® 200 mg/day may increase plasma concentrations of medicinal products transported by OAT3. BRIVIACT® plasma concentrations are decreased when co-administered with strong enzyme inducing antiepileptic drugs (carbamazepine, phenobarbital, phenytoin) but no dose adjustment is required. **Effects on ability to drive and use machines** BRIVIACT®, has minor or moderate influence on the ability to drive and use machines. Patients should be advised not to drive a car or to operate other potentially hazardous machines until they are familiar with the effects of BRIVIACT®, on their ability to perform such activities. **Undesirable effects.** The most frequently reported adverse reactions with BRIVIACT® (reported by >10% of patients) were somnolence (14.3%) and dizziness (11.0%). They were usually mild to moderate in intensity. Somnolence and fatigue (8.2 %) were reported at higher incidences with increasing dose. Very common adverse reactions (≥1% to <10%) were influenza, decreased appetite, depression, anxiety, insomnia, irritability, convulsion, vertigo, upper respiratory tract infections, cough, nausea, vomiting, constipation and fatigue. Neutropenia has been reported in 0.5% (6/1,099) BRIVIACT® patients and 0% (0/459) placebo-treated patients. Four of these patients had decreased neutrophil counts at baseline, and experienced additional decrease in neutrophil counts after initiation of BRIVIACT®. None of the six cases were severe,

required any specific treatment, led to BRIVIACT® discontinuation or had associated infections. Suicidal ideation was reported in 0.3 % (3/1099) of BRIVIACT® treated patients and 0.7 % (3/459) of placebo-treated patients. In short-term clinical studies of BRIVIACT® in patients with epilepsy, there were no cases of completed suicide and suicide attempt, however both were reported in the long-term open-label extension studies. Reactions suggestive of immediate (Type I) hypersensitivity have been reported in a small number of BRIVIACT® patients (9/3022) during clinical development. The safety profile of brivaracetam observed in children was consistent with the safety profile observed in adults. In the open label, uncontrolled, long-term studies suicidal ideation was reported in 4.7 % of paediatric patients (more common in adolescents) compared with 2.4 % of adults and behavioural disorders were reported in 24.8 % of paediatric patients compared with 15.1 % of adults. The majority of events were mild or moderate in intensity, were non-serious, and did not lead to discontinuation of study drug. An additional adverse reaction reported in children was psychomotor hyperactivity (4.7 %). There are limited safety data from open-label studies in children from 1 month to <4 years of age. Limited data are available on neurodevelopment in children <4 years of age. No clinical data are available in neonates. **Overdose** There is limited clinical experience with BRIVIACT® overdose in humans. Somnolence and dizziness were reported in a healthy subject taking a single dose of 1,400 mg of BRIVIACT®. The following adverse reactions were reported with brivaracetam overdose: nausea, vertigo, balance disorder, anxiety, fatigue, irritability, aggression, insomnia, depression, and suicidal ideation in the post-marketing experience. In general, the adverse reactions associated with brivaracetam overdose were consistent with the known adverse reactions. There is no specific antidote. Treatment of an overdose should include general supportive measures. Since less than 10% of BRIVIACT® is excreted in urine, haemodialysis is not expected to significantly enhance BRIVIACT® clearance.

Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: 22 November 2021

<http://www.ema.europa.eu/>

About BRIVIACT® (brivaracetam) CV in the U.S.⁵

BRIVIACT was approved in the U.S. in 2016 as an add-on therapy for adult patients with partial-onset seizures. BRIVIACT was approved as monotherapy for adults in September 2017, and as monotherapy or adjunctive therapy in patients four years of age and older with partial-onset seizures in 2018. In August 2021, BRIVIACT was approved for the treatment of partial-onset seizures in patients as young as one month of age. BRIVIACT is available in three formulations: oral tablets, oral solution, and intravenous (IV) injection. More information is available at [Drugs@FDA: FDA-Approved Drugs](#).

BRIVIACT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Suicidal Behavior and Ideation:** Antiepileptic drugs, including BRIVIACT, increase the risk of suicidal behavior and ideation. Monitor patients taking BRIVIACT for the emergence or worsening of depression; unusual changes in mood or behavior; or suicidal thoughts, behavior,

or self-harm. Advise patients, their caregivers, and/or families to be alert for these behavioral changes and report them immediately to a healthcare provider.

- **Neurological Adverse Reactions:** BRIVIACT causes somnolence, fatigue, dizziness, and disturbance in coordination. Monitor patients for these signs and symptoms and advise them not to drive or operate machinery until they have gained sufficient experience on BRIVIACT.
- **Psychiatric Adverse Reactions:** BRIVIACT causes psychiatric adverse reactions, including non-psychotic and psychotic symptoms in adult and pediatric patients. Advise patients to report these symptoms immediately to a healthcare provider.
- **Hypersensitivity:** BRIVIACT can cause hypersensitivity reactions. Bronchospasm and angioedema have been reported. Discontinue BRIVIACT if a patient develops a hypersensitivity reaction after treatment. BRIVIACT is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.
- **Withdrawal of Antiepileptic Drugs:** As with all antiepileptic drugs, BRIVIACT should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus.

ADVERSE REACTIONS

In adult adjunctive therapy placebo-controlled clinical trials, the most common adverse reactions (at least 5% for BRIVIACT and at least 2% more frequently than placebo) were somnolence and sedation, dizziness, fatigue, and nausea and vomiting symptoms. Adverse reactions reported in clinical studies of pediatric patients were generally similar to those in adult patients. Adverse reactions with BRIVIACT injection in adult and pediatric patients were generally similar to those observed with BRIVIACT tablets. Other adverse events that occurred in adult patients who received BRIVIACT injection included dysgeusia, euphoric mood, feeling drunk, and infusion site pain.

BRIVIACT is a Schedule V controlled substance.

Please refer to the full [Prescribing Information](#) and visit www.BRIVIACThcp.com.

About VIMPAT® (lacosamide)

Important Safety Information about VIMPAT® in the EU and EEA⁶

VIMPAT® is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy. VIMPAT® is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 4 years of age with epilepsy and in the treatment of primary generalised tonic-clonic seizures in adults, adolescents and children from 4 years of age with idiopathic generalised epilepsy. VIMPAT® therapy can be initiated with either oral or IV administration. For the paediatric population, the physician should prescribe the most appropriate formulation and strength according to weight and dose. A single loading dose may be initiated in patients in situations when the physician determines that rapid attainment of lacosamide steady state plasma concentration and therapeutic effect is warranted. It should be administered under medical supervision with consideration of the potential for increased incidence of serious cardiac arrhythmia and CNS adverse reactions. Administration of a loading dose has not been studied in acute conditions such as status epilepticus. Use of a loading dose is not recommended in adolescents and children weighing less than 50 kg. Administration of a loading dose has not been

studied in children. A maximum dose of 300 mg/day is recommended for paediatric patients weighing 50 kg or more and for adult patients with mild to moderate hepatic impairment. Based on data in adults, in paediatric patients weighing less than 50 kg with mild to moderate hepatic impairment, a reduction of 25 % of the maximum dose should be applied. Lacosamide should be administered to adult and paediatric patients with severe hepatic impairment only when the expected therapeutic benefits are anticipated to outweigh the possible risks. The dose may need to be adjusted while carefully observing disease activity and potential side effects in the patient. In adolescents and adults weighing 50 kg or more with mild to moderate hepatic impairment a loading dose of 200mg may be considered, but further dose titration (>200 mg daily) should be performed with caution. In paediatric patients weighing 50 kg or more and in adult patients with mild or moderate renal impairment a loading dose of 200 mg may be considered, but further dose titration (> 200 mg daily) should be performed with caution. In paediatric patients weighing 50 kg or more and in adult patients with severe renal impairment (CLCR \leq 30 ml/min) or with end-stage renal disease, a maximum dose of 250 mg/day is recommended and the dose titration should be performed with caution. In paediatric patients weighing less than 50 kg with severe renal impairment (CLCR \leq 30 ml/min) and in those with end-stage renal disease, a reduction of 25 % of the maximum dose is recommended. Contraindications: Hypersensitivity to the active substance or any of the excipients; known second- or third-degree atrioventricular (AV) block. Special warnings and precautions for use: Treatment with VIMPAT[®] has been associated with dizziness which could increase the occurrence of accidental injury or falls. Therefore, patients should be advised to exercise caution until they are familiar with the potential effects of the medicine. New onset or worsening of myoclonic seizures has been reported in both adult and paediatric patients with PGTCS, in particular during titration. In patients with more than one seizure type, the observed benefit of control for one seizure type should be weighed against any observed worsening in another seizure type. Dose-related prolongations in PR interval with VIMPAT[®] have been observed in clinical studies. VIMPAT[®] should be used with caution in patients with underlying proarrhythmic conditions such as patients with known cardiac conduction problems or severe cardiac disease (e.g. myocardial ischaemia/infarction, heart failure, structural heart disease or cardiac sodium channelopathies) or patients treated with medicinal products affecting cardiac conduction, including antiarrhythmics and sodium channel blocking antiepileptic medicinal products, as well as in elderly patients. In these patients it should be considered to perform an ECG before a Vimpat dose increase above 400mg/day and after Vimpat is titrated to steady-state. In the placebo-controlled studies of VIMPAT[®] in epilepsy patients, atrial fibrillation or flutter were not reported; however both have been reported in open-label epilepsy studies and in post-marketing experience. In post-marketing experience, AV block (including second degree or higher AV block) has been reported. In patients with proarrhythmic conditions, ventricular tachyarrhythmia has been reported. In rare cases, these events have led to asystole, cardiac arrest and death in patients with underlying proarrhythmic conditions. Patients should be made aware of the symptoms of cardiac arrhythmia (e.g. slow, rapid or irregular pulse, palpitations, shortness of breath, feeling lightheaded, fainting). Patients should be counselled to seek immediate medical advice if these symptoms occur. Suicidal ideation and behaviour have been reported in patients treated with antiepileptic medicinal products in several indications. Therefore patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. The safety and efficacy of lacosamide in paediatric patients with epilepsy syndromes in which focal and generalised seizures may coexist have not been determined.

VIMPAT[®] syrup contains sodium methyl parahydroxybenzoate (E219) which may cause allergic reactions (possibly delayed). Vimpat Syrup contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. The syrup contains aspartame (E951), a source of phenylalanine, which may be harmful for people with phenylketonuria. Vimpat syrup contains propylene glycol (E1520). VIMPAT[®] syrup contains 1.42 mg sodium per ml, equivalent to 0.07 % of the WHO recommended maximum daily intake of 2 g sodium for an adult. VIMPAT[®] solution for infusion contains 59.8 mg sodium per vial, equivalent to 3% of the WHO recommended maximum daily intake of 2 g sodium for an adult. Effects on ability to drive and use machines: VIMPAT[®] may have minor to moderate influence on the ability to drive and use machines. VIMPAT[®] treatment has been associated with dizziness or blurred vision. Accordingly patients should be advised not to drive a car or to operate other potentially hazardous machinery until they are familiar with the effects of VIMPAT[®] on their ability to perform such activities. Undesirable effects: The most common adverse reactions ($\geq 10\%$) are dizziness, headache, diplopia, and nausea. They were usually mild to moderate in intensity. Some were dose-related and could be alleviated by reducing the dose. Incidence and severity of CNS and gastrointestinal (GI) adverse reactions usually decreased over time. Incidence of CNS adverse reactions such as dizziness may be higher after a loading dose. Other common adverse reactions ($\geq 1\%$ - $< 10\%$) are depression, confusional state, insomnia, balance disorder, myoclonic seizures, ataxia, memory impairment, cognitive disorder, somnolence, tremor, nystagmus, hypoesthesia, dysarthria, disturbance in attention, paraesthesia, vision blurred, vertigo, tinnitus, vomiting, constipation, flatulence, dyspepsia, dry mouth, diarrhoea, pruritus, rash, muscle spasms, gait disturbance, asthenia, fatigue, irritability, feeling drunk, injection site pain or discomfort (local adverse events associated with intravenous administration), irritation (local adverse events associated with intravenous administration), fall, and skin laceration, contusion. The use of VIMPAT[®] is associated with dose-related increase in the PR interval. Adverse reactions associated with PR interval prolongation (e.g. atrioventricular block, syncope, bradycardia) may occur. Additional adverse reactions reported in PGTCs patients were myoclonic epilepsy and ataxia. The most frequently reported adverse reactions were dizziness and somnolence. The most common adverse reactions resulting in discontinuation of lacosamide therapy were dizziness and suicidal ideation. The safety profile of lacosamide in placebo-controlled and in open-label studies (n=408) in adjunctive therapy in children from 4 years of age with partial-onset seizures was consistent with the safety profile observed in adults although the frequency of some adverse reactions (somnolence, vomiting and convulsion) was increased and additional adverse reactions (nasopharyngitis, pyrexia, pharyngitis, decreased appetite, lethargy and abnormal behaviour) have been reported in paediatric patients: nasopharyngitis (15.7 %), vomiting (14.7 %), somnolence (14.0 %), dizziness (13.5 %), pyrexia (13.0 %), convulsion (7.8 %), decreased appetite (5.9 %), pharyngitis (4.7 %), lethargy (2.7 %) and abnormal behaviour (1.7 %).

Laboratory abnormalities: Abnormalities in liver function tests have been observed in placebo-controlled studies with VIMPAT[®] in adult patients with partial-onset seizures who were taking 1-3 concomitant antiepileptic medicinal products. Elevations of ALT to $\geq 3 \times \text{ULN}$ occurred in 0.7% (7/935) of VIMPAT[®] patients and 0% (0/356) of placebo patients. Multiorgan Hypersensitivity Reactions: Multiorgan hypersensitivity reactions (also known as Drug Reaction with Eosinophilia and Systemic Symptoms, DRESS) have been reported in patients treated with some antiepileptic medicinal products. These reactions are variable in expression but typically present with fever and rash and

can be associated with involvement of different organ systems. If multiorgan hypersensitivity reaction is suspected, VIMPAT® should be discontinued.

Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information. Date of revision: 10 June 2021. <http://www.ema.europa.eu/>

About VIMPAT (lacosamide) CV in the U.S.⁷

VIMPAT® was approved in the U.S. in 2008 as an add-on therapy for the treatment of partial-onset seizures in adult patients with epilepsy. VIMPAT was approved as monotherapy for adults in August 2014, and as monotherapy or adjunctive therapy in patients four years of age and older with partial-onset seizures in 2017. In 2020, it was approved adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in patients four years of age and older and VIMPAT injection for intravenous use in children four years of age and older. In October 2021, VIMPAT received an expanded indication to treat partial-onset seizures in patients as young as one month of age. VIMPAT is available in three formulations: oral tablets, oral solution, and intravenous (IV) injection.

VIMPAT IMPORTANT SAFETY INFORMATION

VIMPAT® is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

VIMPAT is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients 4 years of age and older.

VIMPAT is associated with important warnings and precautions including suicidal behavior and ideation, dizziness and ataxia, cardiac rhythm and conduction abnormalities, syncope, and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as multi-organ hypersensitivity.

Partial-Onset Seizures

In the adult adjunctive placebo-controlled trials for partial-onset seizures, the most common adverse reactions ($\geq 10\%$ and greater than placebo) were dizziness, headache, nausea, and diplopia. In the adult monotherapy clinical trial, adverse reactions were generally similar to those observed and attributed to drug in adjunctive placebo-controlled trials, with the exception of insomnia (observed at a higher rate of $\geq 2\%$).

Primary Generalized Tonic-Clonic Seizures

In the adjunctive therapy placebo-controlled trial for primary generalized tonic-clonic seizures, the adverse reactions were generally similar to those that occurred in the partial-onset seizures trials. The adverse reactions most commonly reported were dizziness, somnolence, headache, and nausea.

Pediatric Patients

Adverse reactions reported in clinical studies for partial-onset seizures in patients 1 month to less than 17 years of age and for primary generalized tonic-clonic seizures for patients 4 to less than 17 years of age were similar to those seen in adult patients.

Injection

In adult adjunctive therapy clinical trials for partial-onset seizures, adverse reactions with intravenous administration generally were similar to those that occurred with the oral formulation, although intravenous administration was associated with local adverse reactions such as injection site pain or discomfort (2.5%), irritation (1%), and erythema (0.5%). When administering a loading dose, the incidence of CNS adverse reactions, such as dizziness, somnolence, and paresthesia, may be higher with 15-minute administration than over a 30- to 60-minute period. The adverse reactions associated with VIMPAT injection in adult patients with primary generalized tonic-clonic seizures are expected to be similar to those seen in adults with partial-onset seizures. The adverse reactions associated with VIMPAT injection in pediatric patients are expected to be similar to those noted in adults. Infusion times less than 30 minutes were not adequately studied in pediatric patients.

VIMPAT is a Schedule V controlled substance.

Please refer to the full [Prescribing Information](#) and visit VIMPAThcp.com.

About NAYZILAM® (midazolam) nasal spray, CIV in the U.S.⁸

NAYZILAM is a benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

NAYZILAM IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NAYZILAM is contraindicated in patients with acute narrow-angle glaucoma.

RISKS FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines, including NAYZILAM, and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

ABUSE, MISUSE, AND ADDICTION

The use of benzodiazepines, including NAYZILAM, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing NAYZILAM and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.

DEPENDENCE AND WITHDRAWAL REACTIONS AFTER USE OF NAYZILAM MORE FREQUENTLY THAN RECOMMENDED

The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although NAYZILAM is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of NAYZILAM may precipitate acute withdrawal reactions, which can be life-threatening. For patients using NAYZILAM more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue NAYZILAM.

Risks of Cardiorespiratory Adverse Reactions

Serious cardiorespiratory adverse reactions have occurred after administration of midazolam. Warn patients and caregivers about the risks of respiratory depression, cardiac and respiratory arrest. Respiratory depression was observed with the administration of NAYZILAM during clinical trials. Cardiac or respiratory arrest caused by NAYZILAM was not reported during clinical trials.

Central Nervous System Depression from Concomitant Use with Other Central Nervous System Depressants, or Moderate or Strong CYP3A4 Inhibitors

Drug products containing midazolam, including NAYZILAM, have a central nervous system (CNS) depressant effect.

Risks from Concomitant Use with Other CNS Depressants

NAYZILAM may cause an increased CNS-depressant effect when used with alcohol or other CNS depressants (e.g., opioids). Warn patients and caregivers that the use of NAYZILAM in combination with alcohol or other CNS depressant drugs may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect.

Risks from Concomitant Use with Moderate or Strong CYP3A4 Inhibitors

Concomitant use of NAYZILAM with moderate or strong CYP3A4 enzyme inhibitors may result in prolonged sedation because of a decrease in plasma clearance of midazolam. Caution patients against engaging in hazardous occupations requiring mental alertness, such as operating machinery, driving a motor vehicle or riding a bicycle until they have completely returned to their level of baseline functioning.

Suicidal Behavior and Ideation

Antiepileptic drugs (AEDs), including NAYZILAM, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Monitor patients treated with NAYZILAM for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to the healthcare provider.

Impaired Cognitive Function

Midazolam, including NAYZILAM, is associated with a high incidence of partial or complete impairment of recall for several hours following an administered dose. Counsel patients on when they can engage in activities requiring complete mental alertness, operate hazardous machinery, or drive a motor vehicle after taking NAYZILAM.

Glaucoma

Benzodiazepines, including NAYZILAM, can increase intraocular pressure in patients with glaucoma. NAYZILAM may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. NAYZILAM is contraindicated in patients with narrow-angle glaucoma.

ADVERSE REACTIONS

In the randomized, double-blind, placebo-controlled trial, the most common adverse reactions ($\geq 5\%$ in any NAYZILAM treatment group) were somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea.

NAYZILAM is a Schedule IV controlled substance.

Please refer to the full [Prescribing Information](#).

For additional medical information about NAYZILAM, patient assistance, or any other information please [visit our website](#) or call ucbCARES at 1-844-599-2273.

Forward looking statements UCB

This press release contains forward-looking statements including, without limitation, statements containing the words “believes”, “anticipates”, “expects”, “intends”, “plans”, “seeks”, “estimates”, “may”, “will”, “continue” and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws, and hiring and retention of its employees. There is no guarantee that new product candidates will be discovered or identified in the

pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.

Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.

Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.

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