UCB News

# UCB shares leading scientific research and advances at American Epilepsy Society Annual Meeting

- **Phase 3 CDKL5 deficiency disorder (CDD) results:** UCB shares 21 scientific abstracts, including the presentation of positive primary efficacy and safety results from a phase 3 study of FINTEPLA®▲ (fenfluramine)[1] in CDD, marking the third developmental and epileptic encephalopathy (DEE) to see positive results following Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS).[2]
- **Open-label extension study for fenfluramine:** Sustained long-term safety and clinical benefit - as assessed by investigator and caregiver reported Clinical Global Impression-Improvement (CGI) ratings - in patients living with DS and LGS.[3]
- **Developmental and epileptic encephalopathies survey:** Interim caregiver survey data highlight the significant impact of disruptive seizures on individuals living with DEEs and their caregivers, emphasizing the importance of support for families managing developmental and epileptic encephalopathies.[4]
- **Prolonged seizures:** Studies underscore the significant burden and risks of prolonged seizures, highlighting the need for swift intervention and improved treatment options to prevent escalation and enhance outcomes.[5,6,7,8]

**Brussels, Belgium – December 4 2025 – 7:00AM CET –** UCB, a global biopharmaceutical company, today announced it will present 21 abstracts at the American Epilepsy Society (AES) Annual Meeting (December 5-9, 2025). Data include primary efficacy and safety results from a Phase 3 study of fenfluramine in CDD, final results from a long-term open-label extension study of fenfluramine in DS and LGS, findings on the disease burden of developmental and epileptic encephalopathies (DEEs), and research on prolonged seizures.[2,3,4,5,6,7,8]

Dimitrios Bourikas, Global Medical Head, DEE and Epilepsy, UCB, commented: "Sharing these new data at AES 2025 reflects UCB's unwavering dedication to addressing the needs of people living with epilepsy and those who support them. By highlighting clinical outcomes and the experiences of patients and caregivers, we hope to inform better care and support, with the ultimate goal of creating a future where nobody facing a debilitating epileptic condition is left behind."

## Highlights of data to be presented at AES 2025:

### Fenfluramine in CDKL5 deficiency disorder: Primary positive phase 3 results[2*]

A phase 3, randomized, placebo-controlled trial shows that fenfluramine provided significantly greater reduction in countable motor seizure frequency compared with placebo in patients with CDKL5 deficiency disorder. Treatment emergent adverse events (TEAEs) are consistent with the known safety profile of fenfluramine in DS and LGS.

*The safety and efficacy of fenfluramine for the treatment of CDD has not been established and is not currently approved for use by any regulatory authority worldwide. In the US, Fintepla (fenfluramine) is indicated for the

treatment of seizures associated with DS and LGS in patients 2 years of age and older.[9] In the EU, it is indicated for the treatment of seizures associated with DS and LGS as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older.[1]

**Final Results From a Long-Term Open-Label Extension Study of Fenfluramine (Up to 4 Years)[3]**
These data show a consistent rate of TEAEs with previous DS and LGS Phase 3 studies as well as an improvement or no change in CGI-I ratings from baseline by caregivers and investigators.

**Impact of disruptive seizures on daily functioning[4]**
Interim results from a large caregiver survey highlight that disruptive seizures, sleep disturbances and challenging behaviors from those living with DEEs have a substantial impact on both activities of daily living and ability to communicate. The data underscore the ongoing burden on individuals living with DEEs and their caregivers, emphasizing the need for holistic support and care strategies.

**Prolonged seizures**

- Real-world study of patients in the United States highlight that those experiencing prolonged seizures are at an increased risk for serious complications, including progression to status epilepticus and a need to frequently require emergency healthcare.[5]
- Interviews with patients and caregivers indicate a clear preference for acute seizure medications that can be administered quickly and act rapidly at seizure onset.[7] A further quantitative survey of adults and adolescents with epilepsy and caregivers reveal that the highest priorities for acute seizure medications are fast onset of action (within 1-2 minutes) and non-rectal, user-friendly administration routes.[8]

**UCB abstracts during AES 2025:**

| Lead Author | Abstract Title |
|---|---|
| **Fenfluramine** | |
| Specchio N, et al.[2] | Fenfluramine in CDKL5 deficiency disorder: primary efficacy and safety results from a phase 3, randomized, double-blind, placebo-controlled study |
| Strzelczyk A, et al.[10] | Healthcare Resource Utilization and Antiseizure Medication Claims in Patients With Lennox-Gastaut Syndrome Receiving Fenfluramine in the United States |
| Kerr W, et al.[11] | Fenfluramine Persistence in Patients With Lennox-Gastaut Syndrome: A Retrospective Analysis Using US Claims Data |
| Breuillard D, et al.[12] | Association of Fenfluramine Treatment and Everyday Executive Functioning in Adult Patients With Lennox-Gastaut Syndrome |
| Gil-Nagel A, et al.[3] | Final Results From a Long-Term Open-Label Extension Study (Up to 4 Years): Tolerability of Fenfluramine and Global Functioning of Pediatric and Adult Patients With Dravet or Lennox-Gastaut Syndromes |
| **Developmental and Epileptic Encephalopathies (DEEs)** | |
| Donner E, at al. [13] | Mortality Rates and Risk Factors Among Patients With Lennox-Gastaut Syndrome (LGS) or Dravet Syndrome (DS) |
| Bailey L, et al.[4] | Impacts of Disruptive Seizures, Sleep, and Behaviors on Activities of Daily Living and Communication in Developmental and Epileptic Encephalopathies: Interim Results of a Caregiver Survey |
| Meer N, et al. [14] | Streamlining The Process of Caregiving for a Loved One with Dravet or Lennox-Gastaut Syndrome |
| **Brivaracetam** | |

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| Fujimoto A, et al.[15] | Tolerability and Efficacy of Adjunctive Brivaracetam in Japanese and Chinese Patients With Focal Seizures: Phase 3, Open-Label Extension Trial |
| Leanca M, et al.[16] | Long-Term Safety, Tolerability, and Efficacy of Brivaracetam in Patients With Childhood Absence Epilepsy or Juvenile Absence Epilepsy |
| Kimiskidis V, et al.[17] | Digital Application Usage in Epilepsy: Insights From Real-World Setting Studies BRIVA-Reg and BRITOBA |
| **Lacosamide** | |
| McClung C, et al.[18] | Long-Term Use of Oral Lacosamide in Young Children With Epilepsy Who Received Lacosamide in Previous Trials: Data From a Multicenter, Open-Label, Follow-Up Trial |
| Moseley B, et al.[19] | Efficacy, Safety, and Pharmacokinetics of Lacosamide in Neonates With Seizures: Results of a Phase 2/3, Open-Label, Randomized, Active Comparator Trial |
| **Midazolam Nasal Spray** | |
| Morris G, et al.[20] | Healthcare Resource Utilization and Costs With the Introduction of Intranasal Midazolam in Acute Seizure Management: A Wisconsin-Based Claims Analysis |
| **Prolonged seizures** | |
| Trinka E, et al.[5] | Describing the Population of Patients With Prolonged Seizures: US Subgroup Results From a Global Real-World Point-In-Time Study |
| Kaye D, et al. [6] | Bridging the Divide: Enhancing Communication and Care Between People Living With Epilepsy and Their Healthcare Providers |
| Ho K-A, et al.[7] | Patient and Caregiver Perceptions of Acute Seizure Medications and the Rapid and Early Seizure Termination (REST) Approach: Qualitative Interviews |
| Laloyaux C, et al.[8] | Patient and Caregiver Preferences for Acute Seizure Medications: A Quantitative Survey |
| **Early pipeline and exploratory research** | |
| Wolff C, et al.[21] | AAV Mediated Overexpression of STXBP1 Variants in a Mouse Model of STXBP1 Haploinsufficiency |
| Rodriguez N, et al.[22] | AAV Gene Therapy in Juvenile Mice of STXBP1 Haploinsufficiency |
| Rajman M, et al.[23] | Reactive Mouse Primary Astrocytes as a Model to Explore Glial Gene Expression Profiles Identified in Human Temporal Lobe Epilepsy |

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**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 approximately 9,000 people in approximately 40 countries, the company generated revenue of €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

**Forward looking statements**
This press release may contain 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: the global spread and impact of COVID-19, 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, will progress to product approval 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 differences 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's 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 it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB 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.

**Important Safety Information about FINTEPLA▼ (fenfluramine) in the EU**[1]

**Indications:** Treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older.

**Dosage and Administration:** Please refer to SmPC for full information. Should be initiated and supervised by physicians with experience in the treatment of epilepsy. Fintepla is prescribed and dispensed according to the Fintepla controlled access programme. Dravet syndrome: Patients who are **not** taking stiripentol: Starting dose is 0.1 mg/kg twice daily (0.2 mg/kg/day). After 7 days, if tolerated, can increase dose to 0.2 mg/kg twice daily (0.4 mg/kg/day). After an additional 7 days, if tolerated and further seizure reduction required, can increase dose to a maximum of 0.35 mg/kg twice daily (0.7 mg/kg/day), which is the recommended maintenance dose. Patients requiring more rapid titration may increase the dose every 4 days. Do not exceed maximum daily dose of 26 mg (13 mg twice daily). Patients who are taking stiripentol: Starting dose is 0.1 mg/kg twice daily (0.2 mg/kg/day). After 7 days, if tolerated, can increase dose to 0.2 mg/kg twice daily (0.4 mg/kg/day), which is the recommended maintenance dose. Patients requiring more rapid titration may increase the dose every 4 days. Do not exceed a total dose of 17 mg (8.6 mg twice daily). Lennox-Gastaut syndrome: Starting dose is 0.1 mg/kg twice daily (0.2 mg/kg/day). After 7 days, the dose should be increased to 0.2 mg/kg twice daily (0.4 mg/kg/day), if tolerated. After an additional 7 days, if tolerated, dose should be increased to 0.35 mg/kg twice daily (0.7 mg/kg/day), which is the recommended maintenance dose. Do not exceed maximum daily dose of 26 mg (13 mg twice daily). **Discontinuation:** When discontinuing treatment, decrease the dose gradually. As with all anti-epileptic medicines, avoid abrupt discontinuation when possible to minimize the risk of increased seizure frequency and status epilepticus. A final echocardiogram should be conducted 3-6 months after the last dose of treatment with fenfluramine. **Renal impairment:** Generally, no

dose adjustment is recommended when administered to patients with mild to severe renal impairment, however, a slower titration may be considered. If adverse reactions are reported, a dose reduction may be needed. Has not been studied in patients with end-stage renal disease. Not known if fenfluramine or its active metabolite, norfenfluramine, is dialyzable. **Hepatic impairment:** Generally, no dose adjustment is recommended when Fintepla is administered without concomitant stiripentol to patients with mild and moderate hepatic impairment (Child-Pugh Class A and B). In patients with severe hepatic impairment (Child-Pugh C) not receiving concomitant stiripentol, the maximum dosage is 0.2mg/kg twice daily, and the maximal total daily dose is 17 mg. There are limited clinical data on the use of Fintepla with stiripentol in patients with mild impaired hepatic function. A slower titration may be considered in patients with hepatic impairment and a dose reduction may be needed if adverse reactions are reported. No clinical data is available on the use of Fintepla with stiripentol in moderate and severe hepatic impairment, therefore not recommended for use. Elderly: No data available. Paediatric population: Safety and efficacy in children below 2 years of age not yet established. No data available.

**Contraindications:** Hypersensitivity to active substance or any excipients. Aortic or mitral valvular heart disease and pulmonary arterial hypertension. Within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome.

**Warnings and Precautions:** Aortic or mitral valvular heart disease and pulmonary arterial hypertension: Neither pulmonary arterial hypertension nor valvular heart disease were observed during these studies. However, post-marketing data show that they can also occur with doses used to treat Dravet syndrome and Lennox-Gastaut syndrome (see section 4.8). Prior to starting treatment, patients must undergo an echocardiogram to establish a baseline and exclude any pre-existing valvular heart disease or pulmonary hypertension. Conduct echocardiogram monitoring every 6 months for the first 2 years and annually thereafter. If an echocardiogram indicates pathological valvular changes, consider follow-up earlier to evaluate whether the abnormality is persistent. If pathological abnormalities seen on echocardiogram, evaluate the benefit versus risk of continuing fenfluramine treatment with the prescriber, caregiver and cardiologist. Once treatment is discontinued for any reasons, a final echocardiogram should be conducted 3-6 months after the last dose of treatment with fenfluramine. If echocardiogram findings suggestive of pulmonary arterial hypertension, perform a repeat echocardiogram as soon as possible and within 3 months to confirm these findings. If echocardiogram finding is confirmed suggestive of an increased probability of pulmonary arterial hypertension defined as intermediate probability, conduct a benefit-risk evaluation of continuation of Fintepla by the prescriber, carer and cardiologist. If echocardiogram suggests a high probability, it is recommended fenfluramine treatment should be stopped. Decreased appetite and weight loss: Fenfluramine can cause decreased appetite and weight loss - an additive effect can occur in combination with other anti-epileptic medicines such as stiripentol. Monitor the patient's weight. Undertake risk-benefit evaluation before starting treatment if history of anorexia nervosa or bulimia nervosa. Fintepla controlled access programme: A controlled access programme has been created to 1) prevent off-label use in weight management in obese patients and 2) confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking Fintepla. Somnolence: Fenfluramine can cause somnolence which could be potentiated by other central nervous system depressants. Suicidal behaviour and ideation: Suicidal behaviour and ideation have been reported in patients treated with anti-epileptic medicines in several indications. Advise patients and caregivers to seek medical advice should any signs of suicidal behaviour and ideation emerge. Serotonin syndrome: Serotonin syndrome, a potentially life-threatening condition, may occur with fenfluramine treatment, particularly with concomitant use of other serotonergic agents; with agents that impair metabolism of serotonin such as MAOIs; or with antipsychotics that may affect the serotonergic neurotransmitter systems. Carefully observe the patient, particularly during treatment initiation and dose increases. Increased seizure

frequency: A clinically relevant increase in seizure frequency may occur during treatment, which may require adjustment in the dose of fenfluramine and/or concomitant anti-epileptic medicines, or discontinuation of fenfluramine, should the benefit-risk be negative. Cyproheptadine: Cyproheptadine is a potent serotonin receptor antagonist and may therefore decrease the efficacy of fenfluramine. If cyproheptadine is added to treatment with fenfluramine, monitor patient for worsening of seizures. If fenfluramine treatment is initiated in a patient taking cyproheptadine, fenfluramine's efficacy may be reduced. Glaucoma: Fenfluramine can cause mydriasis and can precipitate angle closure glaucoma. Discontinue therapy in patients with acute decreases in visual acuity. Consider discontinuation if ocular pain of unknown origin. Effect of CYP1A2 or CYP2B6 inducers: Co-administration with strong CYP1A2 inducers or CYP2B6 inducers will decrease fenfluramine plasma concentrations, which may lower the efficacy of fenfluramine. If co-administration is considered necessary, the patient should be monitored for reduced efficacy and a dose increase of fenfluramine could be considered provided that it does not exceed twice the maximum daily dose (52 mg/day). If a strong CYP1A2 or CYP2B6 inducer is discontinued during maintenance treatment with fenfluramine, consider gradual reduction of the fenfluramine dosage to the dose administered prior to initiating the inducer. Effect of CYP1A2 or CYP2D6 inhibitors: Initiation of concomitant treatment with a strong CYP1A2 or CYP2D6 inhibitor may result in higher exposure and, therefore, adverse events should be monitored, and a dose reduction may be needed in some patients. Excipients: Contains sodium ethyl para-hydroxybenzoate (E 215) and sodium methyl para-hydroxybenzoate (E 219) - may cause allergic reactions (possibly delayed). It also contains sulfur dioxide (E 220) which may rarely cause severe hypersensitivity reactions and bronchospasm. Patients with rare glucose-galactose malabsorption should not take this medicine. The product contains less than 1 mmol sodium (23 mg) per the maximum daily dose of 12 mL; essentially 'sodium-free'. Contains glucose - may be harmful to teeth. Interactions: Pharmacodynamic interactions with other CNS depressants increase the risk of aggravated central nervous system depression. An increase in dose may be necessary when coadministered with rifampicin or a strong CYP1A2 or CYP2B6 inducer. In in vitro studies coadministration with a strong CYP1A2 or CYP2D6 inhibitor may result in higher exposure (see section 4.4 of the SmPC). Coadministration with CYP2D6 substrates or MATE1 substrates may increase their plasma concentrations. Co-administration with CYP2B6 or CYP3A4 substrates may decrease their plasma concentrations. Pregnancy and lactation: Limited data in pregnant women. As a precaution, avoid use of Fintepla in pregnancy. It is unknown whether fenfluramine/metabolites are excreted in human milk. Animal data have shown excretion of fenfluramine/metabolites in milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Fintepla taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Drive and use machines.: Fintepla has moderate influence on the ability to drive/ use machines as it may cause somnolence and fatigue. Advise patients not to drive or operate machinery until they have sufficient experience to gauge whether it adversely affects their abilities.

**Adverse effects:** Dravet syndrome: Very common (≥1/10): Upper respiratory tract infection, decreased appetite, somnolence, diarrhoea, pyrexia, fatigue, blood glucose decreased, echocardiogram abnormal (Consisted of trace and mild mitral regurgitation, and trace aortic regurgitation, which are considered physiologic). Common (≥1/100 to <1/10): Bronchitis, abnormal behaviour, aggression, agitation, insomnia, mood swings, ataxia, hypotonia, lethargy, seizure, status epilepticus, tremor, constipation, salivary hypersecretion, weight decreased and blood prolactin increased. Lennox-Gastaut syndrome: Very common (≥1/10): Upper respiratory tract infection, decreased appetite, somnolence, diarrhoea, vomiting, fatigue. Common (≥1/100 to <1/10): Bronchitis, influenza, pneumonia, seizure, status epilepticus, lethargy, tremor, constipation, salivary hypersecretion, blood prolactin increased, weight decreased, fall. It is not known whether fenfluramine causes irritability, serotonin syndrome, high blood pressure in the arteries of the lungs (pulmonary arterial hypertension) or heart valve disease. Refer to SmPC for other adverse reactions.

▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

Refer to the European Summary of Product Characteristics for other adverse reactions and full Prescribing Information. https://www.ema.europa.eu/en/documents/product-information/fintepla-epar-product-information_en.pdf.
*FINTEPLA® is a registered trademark of the UCB Group of Companies.*

**Important Safety Information about BRIVIACT® (brivaracetam) in the EU[24]**

**Therapeutic indications:** BRIVIACT is indicated as adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy.

**Posology and method of administration:** The physician should prescribe the most appropriate formulation and strength according to weight and dose. It is recommended to parent and care giver to administer BRIVIACT oral solution with the measuring device (10 ml or 5 ml oral dosing syringe) provided in the carton box. BRIVIACT solution for injection/infusion is an alternative route of administration for patients when oral administration is temporarily not feasible. There is no experience with twice daily intravenous administration of brivaracetam for a period longer than 4 days. Adults: The recommended starting dose is 50 or 100 mg/day based on physician's assessment of required for seizure reduction versus potential side effects. Brivaracetam can be taken with or without food. Based on individual patient response and tolerability, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day. Children and adolescents weighing 50 kg or more: The recommended starting dose is 50 mg/day. Brivaracetam may also be initiated at 100 mg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 100 mg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day. Children and adolescents weighing from 20 kg to less than 50 kg: The recommended starting dose is 1 mg/kg/day. Brivaracetam may also be initiated at doses up to 2 mg/kg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 2 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day to 4 mg/kg/day. Children weighing from 10 kg to less than 20 kg: The recommended starting dose is 1 mg/kg/day. Brivaracetam may also be initiated at doses up to 2.5 mg/kg/day based on physician's assessment of need for seizure control. The recommended maintenance dose is 2.5 mg/kg/day. Based on individual patient response, the dose may be adjusted in the effective dose range of 1 mg/kg/day to 5 mg/kg/day. For adults, adolescents and children from 2 years of age, the dose should be administered in two equally divided doses, approximately 12 hours apart.

If patients miss one dose or more, it is recommended that they take a single dose as soon as they remember and take the following dose at the usual morning or evening time. Brivaracetam oral solution can be diluted in water or juice shortly before swallowing; a nasogastric tube or a gastrostomy tube may also be used. Brivaracetam may be initiated with either intravenous or oral administration. When converting from oral to intravenous administration or vice versa, the total daily dose and frequency of administration should be maintained. Brivaracetam may be administered as an intravenous bolus without dilution or diluted in a compatible diluent and administered as a 15-minute intravenous infusion. This medicinal product must not be mixed with other medicinal products. Brivaracetam bolus injection or intravenous infusion has not been studied in acute conditions, e.g. status epilepticus, and is therefore not recommended for such conditions. For

patients from 16 years of age, if brivaracetam has to be discontinued, it is recommended that the dose is reduced gradually by 50 mg/day on a weekly basis. For patients below the age of 16 years, if brivaracetam has to be discontinued, it is recommended that the dose is reduced by a maximum of half the dose every week until a dose of 1 mg/kg/day (for patients with a body weight less than 50 kg) or 50 mg/day (for patients with body weight of 50 kg or more) is reached. After 1 week of treatment at 50 mg/day, a final week of treatment at 20 mg/day is recommended. No dose adjustment is needed for elderly patients (≥65 years of age) or for those with renal impairment. Based on data in adults, no dose adjustment is necessary in paediatric patients with impaired renal function. No clinical data are available on paediatric patients with renal impairment. Brivaracetam is not recommended for patients with end-stage renal disease undergoing dialysis due to lack of data. Exposure to brivaracetam was increased in patients with chronic liver disease. In patients with hepatic impairment, the following adjusted doses, administered in 2 divided doses, approximately 12 hours apart, are recommended for all stages of hepatic impairment: In adults, adolescents and children weighing ≥50 kg, a 50 mg/day starting dose is recommended, with a maximum daily dose of 150 mg/day. For adolescents and children weighing from 20 kg to <50 kg, a 1 mg/kg/day is recommended, with a maximum daily dose of 3 mg/kg/day. For children weighing from 10 kg to <20 kg, a 1 mg/kg/day is recommended, with a maximum daily dose of 4 mg/kg/day. No clinical data are available in paediatric patients with hepatic impairment. The efficacy of brivaracetam in paediatric patients aged less than 2 years has not yet been established.

**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 brivaracetam. Patients should be monitored for signs of suicidal ideation and behaviours 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. Clinical data on the use of brivaracetam in patients with pre-existing hepatic impairment are limited. Dose adjustments are recommended for patients with hepatic impairment. Brivaracetam film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take brivaracetam. 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'. Brivaracetam oral solution contains 168 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). **Interaction with other medicinal products and other forms of interaction:** In clinical studies, although patient numbers were limited, brivaracetam had no observed benefit over placebo among patients taking concomitant levetiracetam. No additional safety or tolerability concern was observed. In an interaction study between brivaracetam 200 mg single dose and ethanol 0.6 g/L continuous infusion in healthy volunteers, there was no pharmacokinetic interaction, but the effect of alcohol on psychomotor function, attention and memory was approximately doubled with the intake of brivaracetam. Intake of brivaracetam with alcohol is not recommended. In vitro data suggest that brivaracetam has a low interaction potential. The main disposition pathway of brivaracetam® is by CYPindependent hydrolysis; a second pathway involves hydroxylation mediated by CYP2C19. Brivaracetam plasma concentrations may increase when co-administered with CYP2C19 strong inhibitors (e.g. fluconazole, fluvoxamine), but the risk of a clinically relevant CYP2C19 mediated interaction is considered to be low. 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 the strong enzyme inducer rifampicin (600 mg/day for 5 days), decreased brivaracetam area under the plasma concentration curve (AUC)

by 45%. Prescribers should consider adjusting the dose of brivaracetam in patients starting or ending treatment with rifampicin. Brivaracetam plasma concentrations are decreased when co-administered with strong enzyme-inducing AEDs (carbamazepine, phenobarbital, phenytoin) but no dose adjustment is required. Other strong enzyme inducers such as St John's wort (Hypericum perforatum) may decrease the systemic exposure of brivaracetam. Starting or ending treatment with St John's wort should be done with caution. Brivaracetam at 50 or 150 mg/day did not affect the AUC of midazolam (metabolised by CYP3A4). The risk of clinically relevant CYP3A4 interactions is considered low. In vitro studies have shown that brivaracetam exhibits little or no inhibition of CYP450 isoforms except for CYP2C19 and may therefore increase plasma concentrations of medicinal products metabolised by CYP2C19 (e.g. lansoprazole, omeprazole, diazepam). Brivaracetam did not induce CYP1A1/2 but induced CYP3A4 and CYP2B6 in vitro. No CYP3A4 induction was found in vivo. CYP2B6 induction has not been investigated in vivo and brivaracetam may decrease plasma concentrations of medicinal products metabolised by CYP2B6 (e.g. efavirenz). In vitro interaction studies to determine the potential inhibitory effects on transporters concluded that there were no clinically relevant effects, except for OAT3. In vitro, brivaracetam inhibits OAT3 with a half maximal inhibitory concentration 42-fold higher than the Cmax at the highest clinical dose. Brivaracetam 200 mg/day may increase plasma concentrations of medicinal products transported by OAT3. Brivaracetam is a moderate reversible inhibitor of epoxide hydrolase, resulting in an increased concentration of carbamazepine epoxide, an active metabolite of carbamazepine. In controlled clinical studies, carbamazepine epoxide plasma concentration increased by a mean of 37%, 62% and 98% with little variability at Brivaracetam doses of 50 mg/day, 100 mg/day and 200 mg/day, respectively. No safety risks were observed. There was no additive effect of brivaracetam and valproate on the AUC of carbamazepine epoxide. No dose adjustment is needed when brivaracetam is co-administered with carbamazepine, phenobarbital or phenytoin. Brivaracetam had no clinically relevant effect on the plasma concentrations of clobazam, clonazepam, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, phenobarbital, phenytoin, pregabalin, topiramate, valproic acid or zonisamide. There are no data available on the effects of clobazam, clonazepam, lacosamide, pregabalin or zonisamide on brivaracetam plasma concentrations. Co-administration of brivaracetam (100 mg/day) with an oral contraceptive containing ethinylestradiol (0.03 mg) and levonorgestrel (0.15 mg) did not influence the pharmacokinetics of either substance. However, when brivaracetam was coadministered at a dose of 400 mg/day (twice the recommended maximum daily dose), a reduction in estrogen and progestin AUCs of 27% and 23%, respectively, was observed without impact on suppression of ovulation. **Pregnancy:** Data on the use of brivaracetam in pregnant women are limited. There are no data on placental transfer in humans, but brivaracetam was shown to readily cross the placenta in rats. The potential risk for humans is unknown. Animal studies did not detect any teratogenic potential of brivaracetam. In clinical studies, adjunctive brivaracetam used concomitantly with carbamazepine induced a dose-related increase in the concentration of the active metabolite, carbamazepine-epoxide. There are insufficient data to determine the clinical significance of this effect in pregnancy. Brivaracetam should not be used during pregnancy unless clinically necessary. **Breast-feeding:** Brivaracetam is excreted in human breast milk. The decision to discontinue either breastfeeding or brivaracetam should be made based on the benefit of the medicinal product to the mother. In case of co-administration of brivaracetam and carbamazepine, the amount of carbamazepine-epoxide excreted in breast milk could increase. The clinical significance remains unknown. **Fertility:** No human data on the effect of brivaracetam on fertility are available. There was no effect on fertility in rats. **Effects on ability to drive and use machines**: Brivaracetam 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 brivaracetam on their ability to perform such activities. **Undesirable effects:** The most frequently reported adverse reactions with brivaracetam were somnolence (14.3%) and dizziness (11.0%); they were usually mild-to-moderate in intensity. Somnolence and fatigue were reported at a higher incidence with increasing dose. Very common adverse reactions (≥1%-<10%) were

influenza, decreased appetite, depression, anxiety, insomnia, irritability, convulsion, vertigo, upper respiratory tract infections, cough, nausea, vomiting, constipation and fatigue. Neutropenia was reported in 6/1099 (0.5%) of brivaracetam and none (0/459) of the placebo-treated patients. Four of these subjects had decreased neutrophil counts at baseline. None of the neutropenia cases were severe, required any specific treatment or led to discontinuation of brivaracetam and none had associated infections. Suicidal ideation was reported in 0.3% (3/1099) of brivaracetam and 0.7% (3/459) of placebo-treated patients. In short-term clinical studies of brivaracetam in patients with epilepsy, there were no cases of completed suicide and suicide attempt; however, both were reported in open-label extension studies. The safety profile of brivaracetam observed in children from 1 month of age 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 (assessed from 6 years onwards, 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 %). No specific pattern of adverse event (AE) was identified in children from 1 month to < 4 years of age when compared to older paediatric age groups. No significant safety information was identified indicating the increasing incidence of a particular AE in this age group. As data available in children younger than 2 years of age are limited, brivaracetam is not indicated in this age range. Limited clinical data are available in neonates. Reactions suggestive of immediate (Type I) hypersensitivity have been reported in a small number of brivaracetam patients (9/3022) during clinical development. **Overdose:** There is limited clinical experience with brivaracetam overdose in humans. Somnolence and dizziness have been reported in a healthy subject taking a single dose of 1,400 mg of brivaracetam. The following adverse reactions were reported with brivaracetam overdose: nausea, vertigo, balance disorder, anxiety, fatigue, irritability, aggression, insomnia, depression, and suicidal ideation in the postmarketing experience. In general, the adverse reactions associated with brivaracetam overdose were consistent with the known adverse reactions. There is no specific antidote for overdose with brivaracetam. Treatment of an overdose should include general supportive measures. Since <10% of brivaracetam is excreted in urine, haemodialysis is not expected to significantly enhance brivaracetam clearance.

Refer to the European Summary of Product Characteristics for other adverse reactions and full Prescribing Information. https://www.ema.europa.eu/en/documents/product-information/briviact-epar-product-information_en.pdf

*BRIVIACT® is a registered trademark of the UCB Group of Companies.*

**Important Safety Information about VIMPAT® (lacosamide) in the EU[25]**

**Therapeutic indications**: VIMPAT® is indicated as monotherapy in the treatment of partial-onset seizures with or without secondary generalisation in adults, adolescents and children from 2 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 2 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.

**Posology and method of administration**: Lacosamide therapy can be initiated with either oral administration (either tablets or syrup) or IV administration (solution for infusion). The physician should prescribe the most appropriate formulation and strength according to weight and dose. A 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 Central Nervous System (CNS) adverse reactions. Administration of a loading dose has not been studied in acute conditions such as status epilepticus. Administration of a loading dose has not been studied in children. Use of a loading dose is not recommended in adolescents and children weighing less than 50 kg. No dose adjustment is necessary in mildly and moderately renally impaired adult and paediatric patients (CLCR > 30 ml/min). 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 ≤ 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 ≤ 30 ml/min) and in those with end-stage renal disease, a reduction of 25 % of the maximum dose is recommended. 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. Lacosamide is not recommended for use in children below the age of 4 years in the treatment of primary generalized tonic-clonic seizures and below the age of 2 years in the treatment of partial-onset seizures as there are limited data on safety and efficacy in these age groups. **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**: 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 behaviour 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. Dose-related prolongations in PR interval with lacosamide have been observed in clinical studies. Lacosamide should be used with caution in patients with underlying proarrhythmic conditions such as known cardiac conduction problems or severe cardiac diseases (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 electrocardiogram (ECG) before a lacosamide dose increase above 400mg/day and after lacosamide is titrated to steady-state. In the placebo-controlled clinical studies of lacosamide 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. Treatment with lacosamide 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 primary generalized tonic-clonic seizures (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. 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. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age. 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**: Lacosamide may have minor to moderate influence on the ability to drive and use machines. Lacosamide 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 lacosamide on their ability to perform such activities. **Undesirable effects**: The most frequently reported adverse reactions (≥10%) are dizziness, headache, nausea and diplopia. 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 (≥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 and contusion. The use of lacosamide 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. 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, lacosamide should be discontinued. The safety profile of lacosamide in adjunctive therapy in paediatric patients with partial-onset seizures was consistent with the safety profile observed in adults. The additional adverse reactions observed in the paediatric population were pyrexia, nasopharyngitis, pharyngitis, decreased appetite, abnormal behaviour and lethargy. Somnolence was reported more frequently in the paediatric population (≥ 1/10) compared to the adult population (≥ 1/100 to < 1/10).

Refer to the European Summary of Product Characteristics for other adverse reactions and full prescribing information.

https://www.ema.europa.eu/en/documents/product-information/vimpat-epar-product-information_en.pdf (Accessed September 2025)

**Indication and Important Safety Information about FINTEPLA® (fenfluramine) in the US[9]**

FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older

Inspired by patients.
Driven by science.

FINTEPLA is available only through a restricted distribution program called the FINTEPLA REMS. Further information is available at www.FinteplaREMS.com or by telephone at +1 877 964 3649.

**IMPORTANT SAFETY INFORMATION**

**BOXED WARNING:** VALVULAR HEART DISEASE and PULMONARY ARTERIAL HYPERTENSION

- FINTEPLA can cause valvular heart disease and pulmonary arterial hypertension.
- Echocardiogram assessments are required before, during, and after treatment with FINTEPLA.
- FINTEPLA is available only through a restricted program called the FINTEPLA REMS.

**CONTRAINDICATIONS**
Hypersensitivity to fenfluramine or any of the excipients in FINTEPLA. Within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome.

**WARNINGS AND PRECAUTIONS**
Decreased Appetite and Decreased Weight: Advise patients that FINTEPLA can cause decreased appetite and decreased weight. Somnolence, Sedation, and Lethargy: Monitor for somnolence and sedation. Advise patients not to drive or operate machinery until they have gained sufficient experience on FINTEPLA. Suicidal Behavior and Ideation: Monitor patients for suicidal behavior and thoughts. Withdrawal of Antiepileptic Drugs: FINTEPLA should be gradually withdrawn to minimize the risk of increased seizure frequency and status epilepticus. Serotonin Syndrome: Advise patients that serotonin syndrome is a potentially life-threatening condition and may occur with FINTEPLA, particularly with concomitant administration of FINTEPLA with other serotonergic drugs. Increase in Blood Pressure: Monitor blood pressure during treatment. Glaucoma: Discontinue therapy in patients with acute decrease in visual acuity or ocular pain.

**ADVERSE REACTIONS**
The most common adverse reactions (incidence at least 10% and greater than placebo) in patients with Dravet Syndrome were decreased appetite; somnolence, sedation, lethargy; diarrhea; constipation; abnormal echocardiogram; fatigue, malaise, asthenia; ataxia, balance disorder, gait disturbance; blood pressure increased; drooling, salivary hypersecretion; pyrexia; upper respiratory tract infection; vomiting; decreased weight; fall; status epilepticus. The most common adverse reactions (incidence at least 10% and greater than placebo) in patients with Lennox-Gastaut syndrome were diarrhea; decreased appetite; fatigue; somnolence; vomiting.

**DRUG INTERACTIONS**
Strong CYP1A2, CYP2B6, or CYP3A Inducers: Coadministration with strong CYP1A2, CYP2B6, or CYP3A inducers will decrease fenfluramine plasma concentrations. If coadministration of a strong CYP1A2, CYP2B6, or CYP3A inducer with FINTEPLA is necessary, monitor the patient for reduced efficacy and consider increasing the dosage of FINTEPLA as needed. If a strong CYP1A2, CYP2B6, or CYP3A inducer is discontinued during maintenance treatment with FINTEPLA, consider gradual reduction in the FINTEPLA dosage to the dose administered prior to initiating the inducer.

Strong CYP1A2 or CYP2D6 Inhibitors: Coadministration with strong CYP1A2 or CYP2D6 inhibitors will increase fenfluramine plasma concentrations. If FINTEPLA is coadministered with strong CYP1A2 or CYP2D6 inhibitors, the maximum daily dosage of FINTEPLA is 20 mg. If a strong CYP1A2 or CYP2D6 inhibitor is discontinued during maintenance treatment with FINTEPLA, consider gradual increase in the FINTEPLA dosage to the dose recommended without CYP1A2 or CYP2D6 inhibitors. If FINTEPLA is coadministered with stiripentol and a strong CYP1A2 or CYP2D6 inhibitor, the maximum daily dosage of FINTEPLA is 17 mg.

Coadministration of FINTEPLA with stiripentol plus clobazam, with or without valproate, increases fenfluramine plasma concentrations. If FINTEPLA is coadministered with stiripentol plus clobazam, the maximum daily dosage of FINTEPLA is 0.2 mg/kg twice daily (maximum daily dosage of 17 mg).

**USE IN SPECIFIC POPULATIONS**
There are no data on FINTEPLA use in pregnant women. Available data from epidemiologic studies with fenfluramine or dexfenfluramine are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. FINTEPLA can cause decreased appetite and decreased weight, monitor for adequate weight gain during pregnancy. In animal studies, administration of fenfluramine throughout organogenesis (rat and rabbit) or throughout gestation and lactation (rat) resulted in adverse effects on development (fetal malformations, embryofetal and offspring mortality and growth impairment) in the presence of maternal toxicity at clinically relevant maternal plasma levels of fenfluramine and its major active metabolite. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

**Indication and Important Safety Information about BRIVIACT® (brivaracetam) in the US[26]**

BRIVIACT® (brivaracetam) CV is indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

**IMPORTANT SAFETY INFORMATION**

BRIVIACT is associated with important warnings and precautions including suicidal behavior and ideation, somnolence, fatigue, dizziness, disturbance in gait and coordination, psychiatric adverse reactions including nonpsychotic and psychotic symptoms, hypersensitivity reactions (bronchospasm and angioedema), and serious dermatologic reactions. BRIVIACT is contraindicated in patients with a prior hypersensitivity reaction to brivaracetam or any of the inactive ingredients.

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.

**Indication and Important Safety Information about VIMPAT® (lacosamide) in the US[27]**

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.

**IMPORTANT SAFETY INFORMATION**

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 (≥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 ≥2%). Pediatric adverse reactions were similar to those seen in adult patients.

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.

VIMPAT contains lacosamide, a Schedule V controlled substance.

Please refer to the full Prescribing Information.

**Indication and Important Safety Information about NAYZILAM® (midazolam) in the US[28]**

NAYZILAM is 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.

**IMPORTANT SAFETY INFORMATION**

NAYZILAM is contraindicated in patients with acute narrow-angle glaucoma. Concomitant use of benzodiazepines, including NAYZILAM, and opioids may result in profound sedation, respiratory depression, coma, and death. The use of benzodiazepines, including NAYZILAM, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. The continued use of benzodiazepines may lead to clinically significant physical dependence. 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. NAYZILAM may cause an increased CNS-depressant effect when used with alcohol or other CNS depressants. Concomitant use with moderate or strong CYP3A4 inhibitors may result in prolonged sedation due to a decrease in plasma clearance of midazolam. Antiepileptic drugs, including NAYZILAM, increase the risk of suicidal ideation and behavior. Midazolam is associated with a high incidence of partial or complete impairment of recall for the next several hours. Benzodiazepines, including NAYZILAM, can increase intraocular pressure in patients with glaucoma. NAYZILAM use during pregnancy can result in neonatal sedation and/or neonatal withdrawal.

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

NAYZILAM is a Schedule IV controlled substance

Please see full Prescribing Information.

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