UCB News

UCB presents positive results from GEMZ phase 3 study at AES showing fenfluramine significantly reduces countable motor seizure frequency in CDKL5 Deficiency Disorder

- **Seizure reduction:** phase 3 study achieved primary endpoint as fenfluramine demonstrated a statistically significant reduction in countable motor seizure frequency (CMSF) compared with placebo[1]
- **Holistic benefit:** secondary endpoints showed significant and clinically meaningful improvements in Clinical Global Impression–Improvement (CGI-I) in patients treated with fenfluramine compared with placebo[1]
- **Fenfluramine was generally well tolerated**, with no new safety signals identified[1]
- **UCB plans to submit for regulatory approval** of fenfluramine for the treatment of seizures associated with CDKL5 Deficiency Disorder (CDD) as soon as possible, marking fenfluramine's third developmental and epileptic encephalopathy (DEE) to be submitted for regulatory approval

Brussels, Belgium December 8th 2025 – 07:00 CET – UCB, a global biopharmaceutical company, today presented positive efficacy and safety results from the GEMZ phase 3 study investigating adjunctive fenfluramine in children and adults with CDKL5 Deficiency Disorder (CDD) at the American Epilepsy Society (AES) meeting, Atlanta, USA, December 5-9, 2025.[1] The trial met its primary endpoint and key secondary endpoints, demonstrating a statistically significant reduction in countable motor seizure frequency (CMSF) and a clinically meaningful improvement on the Clinical Global Impression-Improvement (CGI-I) scale, compared with placebo.[1]

"UCB is proud to share these important results with the medical community at AES, especially given the significant unmet need in CDD. Families affected by this ultra-rare condition face immense daily challenges with frequent, treatment-resistant seizures that are profoundly disruptive to daily life. These trial results emphasize the impact that seizure control can have on the lives of patients and their families, and we look forward to working with health authorities to make this treatment available as soon as possible", **said Fiona du Monceau, Executive Vice President, Patient Evidence, UCB.**

The GEMZ Phase 3 study is a randomized, double-blind, placebo-controlled, fixed-dose, multi-center study examining the efficacy, safety, and pharmacokinetics of adjunctive fenfluramine treatment in 86 children and adults aged 1 – 35 years, with a CDD diagnosis and uncontrolled seizures.[1]

Phase 3 study results

- Patients treated with fenfluramine (n=42) (0.7mg/kg/day, maximum 26 mg/day) experienced a median reduction of 47.6% in CMSF from baseline, compared with a 2.8% for placebo (n=44) ($p<0.001$).[1] This translated into an estimated median reduction of 52.7% (95% CI: −70.0 to −36.7) between treatment groups during a 14-week titration and maintenance period.[1]
- After 14 weeks, 45.2% (n=19) of fenfluramine-treated patients achieved at least 50% reduction in CMSF, compared with only 4.5% (n=2) of patients who received placebo ($p<0.001$).[1]
- Most fenfluramine-treated patients experienced an increase in countable motor seizure-free days, with a median of >6 additional seizure free days a month from baseline compared with placebo[1]
- Investigators rated 38.1% (n=16) of patients on fenfluramine as "much improved" or "very much improved" on the Clinical Global Impression–Improvement scale (CGI-I), compared with 6.8% (n=3) of those on placebo ($p<0.001$).[1]

- According to caregiver's report of improvement, a CGI-I rating of 'much improved' or 'very much improved' was provided by 53.7% (n=22) vs just 2.3% (n=1) in the placebo group (p<0.001).[1]

Fenfluramine was generally well tolerated in the trial, with no new safety signals identified and no cases of valvular heart disease (VHD) or pulmonary arterial hypertension (PAH) occurring.[1] Treatment-emergent adverse events (TEAEs) were consistent with the known safety profile of fenfluramine in Dravet syndrome and Lennox-Gastaut syndrome, with 14.3% (n=6) of patients who received fenfluramine experiencing serious TEAEs* compared to 6.7% (n=3) of patients who received placebo.[1] UCB is currently conducting an open-label, flexible-dose, long-term 54-week extension (52-week OLE treatment period + 2-week taper) phase of the study to characterize the long-term safety profile and tolerability of fenfluramine in children and adult individuals with CDD.[2]

CDD is an ultra-rare, DEE characterized by multiple types of drug-resistant seizures, plus severe global neurodevelopmental delays resulting in intellectual, motor, cortical visual, gastrointestinal and sleep impairments as major features. It is caused by pathogenic variants in the Cyclin Dependent Kinase-like 5 (*CDKL5*) gene located on the X chromosome and affects four times more females than males. It is estimated that CDD affects approximately 1 in 40,000 to 60,000 live births, with a median age of onset of six weeks.[3,4,5,6,7]

In the European Union (EU), fenfluramine is approved for the 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.[8] In the United States, fenfluramine oral solution is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in patients 2 years of age and older.[9] In Japan, fenfluramine is approved for treating seizures associated with Dravet syndrome and Lennox-Gastaut syndrome (LGS) as an add-on therapy to other anti-epileptic medicines for patients 2 years and older.[10] It is not approved for use in CDD by any regulatory authority worldwide.

*Serious TEAEs included urinary tract infection (n=2), metapneumovirus infection (n=1), RSV pneumonia (n=1), decreased appetite (n=1), and dyskinesia (n=1) in patients on FFA, and gastroenteritis and pneumoperitoneum in the 2 patients on PBO

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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 € 6.15 billion in 2024. UCB is listed on Euronext Brussels (symbol: UCB).

UCB Forward Looking Statement
This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "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 guaranteeing 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 be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.

Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, 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, supply chain disruption and business continuity risks; potential or actual data security and data privacy breaches, or disruptions of UCB's information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars or disruptive technologies/business models, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in laws and/or rules pertaining to tax and duties or the administration of such laws and/or rules, and hiring, retention and compliance of 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'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, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving event or risk as mentioned above as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.

UCB expressly disclaims any obligation to update any forward-looking statements in this document, 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.

Important Safety Information about FINTEPLA®▼ (fenfluramine) in the EU[8]

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: 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: 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. Pulmonary arterial hypertension: pulmonary arterial hypertension in a child associated with fenfluramine for Dravet syndrome has been reported post-marketing. The patient discontinued fenfluramine and the reaction resolved post-discontinuation. Valvular heart disease: valvular heart disease in a child associated with fenfluramine for Dravet syndrome has also been reported post-marketing (see 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. 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 (accessed October 2024)

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

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
There is an association between serotonergic drugs with 5-HT2B receptor agonist activity, including fenfluramine (the active ingredient in FINTEPLA), and 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.

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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.

References

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