

March 26, 2024

UCB Japan Obtained Additional Application of Fintepla[®] (fenfluramine) for the Treatment of Seizures Associated with Lennox-Gastaut Syndrome in Japan

Kyoto, Japan, March 26, 2024 - Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced today that UCB Japan Co. Ltd. (UCB Japan; Headquarters: Tokyo; President, Kanako Kikuchi) obtained additional application of Fintepla[®] Oral Solution 2.2mg/mL (generic name; fenfluramine hydrochloride) for the treatment of seizures in patients with Lennox-Gastaut syndrome (LGS) to the Ministry of Health, Labour and Welfare (MHLW) in Japan.

LGS is a severe form of intractable epilepsy that develops in infancy and childhood. It is also a serious disease presenting with a variety of treatment-resistant seizures, mental developmental disorders, and movement disorders. The main types of seizures of LGS are tonic seizure, atypical absence seizure, and atonic seizure. Among them, atonic seizure is a dangerous seizure in which muscle tone is momentarily lost, leading to head or other injuries due to a fall. LGS has been designated as an intractable disease by MHLW, and there are estimated to be about 4,300 patients living with LGS in Japan.

Fintepla[®] possesses dual activities to inhibit seizures: acting as 5-HT (serotonin) releaser with agonist activity at several 5-HT receptors, and as a positive modulator of Sigma-1 receptor. Nippon Shinyaku entered into an exclusive distribution agreement in Japan for Fintepla[®] with Zogenix Inc. (acquired by UCB in 2022) as of March 2019. Based on this agreement, Nippon Shinyaku has been marketing Fintepla[®] as a treatment for seizures associated with Dravet syndrome since November 2022 in Japan. From now on, Nippon Shinyaku will also conduct information provision activities for LGS. Fintepla[®] was designated as an orphan drug by MHLW for the indication of LGS in May 2023.

Nippon Shinyaku is focusing on the field of intractable, rare disorders. With the addition of this new indication, we hope that Fintepla[®] will become a new treatment option for LGS, and contribute to patients and their families as well as healthcare professionals.

Information of package insert (additional part only)

【Indications】

The treatment of seizures associated with following patients as an add-on therapy to anti-epileptic medicines for the patients whose seizures are not controlled by other anti-epileptic medicines.

- Lennox-Gastaut syndrome

【Usage and Dosage】

The initial oral dose of fenfluramine for adults and children aged 2 years and older is 0.2 mg/kg daily in two divided doses and can be increased according to patient's condition up to 0.7 mg/kg daily at an interval of at least one week. The daily dose should not exceed 26 mg.

About Nippon Shinyaku

Based on Nippon Shinyaku's business philosophy, "Helping people lead healthier, happier lives," we aim to be an organization trusted by the community through creating unique medicines that will bring hope to patients and families suffering from illness. Please visit our website (<https://www.nippon-shinyaku.co.jp/english/>) for products or detailed information.

About UCB Japan

UCB Japan (<https://www.ucbjapan.com/>) was established in 1988 as the Japanese subsidiary of UCB, a global biopharmaceutical company headquartered in Brussels, Belgium. The company is developing its pharmaceutical business with a focus on anti-epileptic drugs, rheumatoid arthritis and psoriasis drugs. As a biopharmaceutical leader in creating value for patients, the company aims to provide new treatment options for patients who have not achieved satisfactory improvement with conventional therapies.

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