

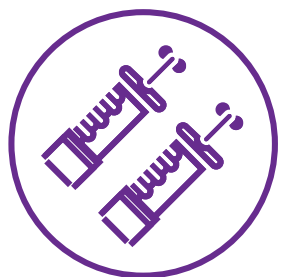


Existing patients shown. Individual patient response to treatment may vary and pictures are representative only.

Fintepla® ▼ (fenfluramine) Dravet syndrome and Lennox-Gastaut syndrome dosing information

Fintepla® (fenfluramine) is indicated 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.¹

Fintepla® offers individualised oral dosing which doesn't impact your current LGS or Dravet syndrome antiseizure regimens¹



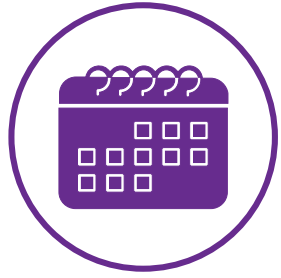
Twice daily dosing



Cherry-flavoured oral solution



Compatible with a ketogenic diet



Dose titrated over 2 weeks



Taken with or without food



Compatible with commercially available gastric and nasogastric feeding tubes

Fintepla® dosing calculation

$$\begin{array}{r} \text{Patient weight (kg)} \\ \times \\ \text{Target twice daily dosage (mg/kg)} \\ \div 2.2 \text{ mg/mL} \\ = \\ \text{Twice daily dose in mL} \end{array}$$

Dravet syndrome patients without stiripentol and LGS patients¹

Maximum dose
13 mg (i.e. 6.0 mL) twice daily
(26 mg/day)

Dravet syndrome patients with stiripentol¹

Maximum dose
8.6 mg (i.e. 4.0 mL) twice daily
(17 mg/day)

Please note that this dosing calculator uses rounded values where appropriate. You should adjust these estimates based on your own clinical experience.

This dosage calculator is not intended to supersede independent clinical judgement or institutional protocols.

The calculated dose should be rounded to the nearest graduated increment.¹

Administration information¹

Fintepla® is packaged with two 3.0 mL oral syringes with 0.1 mL graduations, and two 6.0 mL syringes with 0.2 mL graduations.

If the calculated dose is 3.0 mL or less, the green-printed 3.0 mL syringe should be used.

If the calculated dose is more than 3.0 mL, the purple-printed 6.0 mL syringe should be used.



Fintepla® recommended dosing schedule for children(aged 2 years and older) and adults¹

	Dravet syndrome patients <u>without</u> stiripentol and LGS patients	Dravet syndrome patients <u>with</u> stiripentol
 Starting dose – first week	0.1 mg/kg twice daily (0.2 mg/kg/day)	
 Day 7 – second week*	0.2 mg/kg twice daily (0.4 mg/kg/day)	Maintenance dose 0.2 mg/kg twice daily (0.4 mg/kg/day)
 Day 14*	Maintenance dose 0.35 mg/kg twice daily (0.7 mg/kg/day)	N/A
 Maximal recommended dose	26 mg (13 mg twice daily i.e. 6.0 mL twice daily)	17 mg (8.6 mg twice daily i.e. 4.0 mL twice daily)

*For patients not on concomitant stiripentol requiring more rapid titration, the dose may be increased every 4 days. For patients with Dravet syndrome, dosage may be increased based on clinical response to the maximum recommended dosage, as needed. For patients with Lennox-Gastaut syndrome, dosage should be increased as tolerated to the recommended maintenance dosage (i.e., Day 14)

Contraindications:

Hypersensitivity to the active substance or any of the excipients listed in section 6.1 of the SmPC. Aortic or mitral valvular heart disease. Pulmonary arterial hypertension. Within 14 days of the administration of monoamine oxidase inhibitors due to an increased risk of serotonin syndrome.

Dosing in special populations¹

- Generally, no dose adjustment is recommended when Fintepla is administered to patients for mild and severe renal impairment or mild to moderate hepatic impairment (Child-Pugh Class A & B) without concomitant stiripentol, but a slower titration may be considered. If adverse reactions are reported, a dose reduction may be needed.
- In patients with severe hepatic impairment (Child-Pugh C) not receiving stiripentol, the maximum recommended dosage is 0.2 mg/kg twice daily (maximal total daily dose 17 mg/day)
- Fintepla® is not recommended for use in patients with:
 - Impaired renal function treated with stiripentol
 - Moderate and severe hepatic impairment treated with stiripentol
 - Fintepla has not been studied in patients with end-stage renal disease. It is not known if fenfluramine or its active metabolite norfenfluramine, is dialyzable.

For complete dosing considerations, please consult the Fintepla® Summary of Product Characteristics.

Fintepla® should be initiated and supervised by healthcare professionals with experience in the treatment of epilepsy.

Fintepla® is prescribed and dispensed according to the Fintepla®

Controlled Access Programme (CAP).

The CAP has been created to:

- Prevent off-label use in weight management in obese patients
 - Confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking Fintepla®
- Please refer to the SmPC for further information.

References:

- Fintepla SmPC.
- Abbreviations: LGS, Lennox-Gastaut syndrome.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177.