



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Fintepla (*fenfluramine*)

An overview of Fintepla and why it is authorised in the EU

What is Fintepla and what is it used for?

Fintepla is a medicine used in addition to other epilepsy medicines to treat patients from the age of 2 years who have Dravet syndrome, a type of epilepsy that begins in childhood and can continue into adulthood.

Dravet syndrome is rare, and Fintepla was designated an 'orphan medicine' (a medicine used in rare diseases) on 18 December 2013. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3131219.

Fintepla contains the active substance fenfluramine.

How is Fintepla used?

The medicine can only be obtained by 'special' prescription. This means that it is used under stricter conditions than normal to prevent misuse and to ensure doctors are informed about the need for regular heart checks in patients taking the medicine. Treatment should be started and supervised by a doctor experienced in the treatment of epilepsy.

Fintepla is available as a liquid to be taken by mouth twice a day. The dose depends on the patient's weight and whether the patient is taking stiripentol, another epilepsy medicine, and can be adjusted based on the response to treatment.

For more information about using Fintepla, see the package leaflet or contact your doctor or pharmacist.

How does Fintepla work?

The active substance in Fintepla, fenfluramine, causes the release of serotonin in the brain. Serotonin is a substance used by nerve cells to communicate with neighbouring cells. The exact way that fenfluramine works is not fully understood. It is thought that serotonin acts on several targets in the brain to improve symptoms of patients with Dravet syndrome. Fenfluramine may also protect against seizures by acting on the sigma-1 receptor found on the surface of nerve cells.

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What benefits of Fintepla have been shown in studies?

Studies showed that Fintepla reduces the frequency of seizures in children and young adults with Dravet syndrome taking at least one other epilepsy medicine.

In two main studies in a total of 205 patients comparing Fintepla with placebo (a dummy treatment), both given in addition to the patient's standard of care, the main measure of effectiveness was the change in the monthly number of seizures.

In the first study, the average (median) monthly number of seizures reduced from 21 to 5 in patients treated with Fintepla, and from 34 to 26 in those taking placebo. The study also showed that 73% of patients treated with Fintepla and 10% of those taking placebo had at least a 50% reduction in the monthly number of seizures.

In the second study, patients were also taking stiripentol and at least one other epilepsy medicine. The average (median) monthly number of seizures reduced from 14 to 4 in patients treated with Fintepla and remained at 11 in patients taking placebo. In this study, 55% of patients treated with Fintepla and 9% of those taking placebo had at least a 50% reduction in the monthly number of seizures.

What are the risks associated with Fintepla?

The most common side effects with Fintepla (which may affect more than 1 in 10 people) are decreased appetite, diarrhoea, fever, fatigue (tiredness), upper respiratory tract infection (nose and throat infection), lethargy (lack of energy), somnolence (sleepiness) and bronchitis (chest infection).

For the full list of side effects of Fintepla, see the package leaflet.

Fintepla must not be taken by patients who have heart or lung problems called valvular heart disease or pulmonary hypertension. It must also not be used by patients who have used medicines called monoamine oxidase inhibitors (MAOI), including MAOI antidepressants, in the last 2 weeks.

For the full list of restrictions, see the package leaflet.

Why is Fintepla authorised in the EU?

Dravet syndrome is a rare disease with limited treatment options. Fintepla used in addition to other epilepsy medicines has been shown to reduce the frequency of seizures in children and young adults with the disease. The side effects are considered manageable.

The European Medicines Agency therefore decided that Fintepla's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Fintepla?

Serious cases of heart and lung problems (valvular heart disease and pulmonary arterial hypertension) have been reported with higher doses of the medicine used in the past for the treatment of obesity in adults. Although these effects have not been reported at the lower doses used in patients with Dravet syndrome, several measures have been put in place to minimise this risk:

- The company that markets Fintepla will ensure that a system is put in place to control access to the medicine and prevent misuse. Doctors who are expected to prescribe this medicine will receive educational material with information about monitoring patients' heart function and minimising misuse of the medicine.

- The company that markets Fintepla will also provide doctors with educational materials to give to patients to inform them about the need for heart monitoring and how to detect and manage heart and lung problems, should they occur.
- The company will set up a registry to collect data on the long-term safety of Fintepla, and to assess whether the measures to minimise the risk of serious side effects have worked.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Fintepla have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Fintepla are continuously monitored. Side effects reported with Fintepla are carefully evaluated and any necessary action taken to protect patients.

Other information about Fintepla

Fintepla received a marketing authorisation valid throughout the EU on 18 December 2020.

Further information on Fintepla can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/fintepla.

This overview was last updated in 12-2020.