This guide was approved by the Health Products Regulatory Authority (HPRA). It is intended to ensure that patients and caregivers are familiar with the characteristics of Fintepla®▼ (fenfluramine) and thus reduce the potential risk of certain side effects.

Fintepla®▼ (fenfluramine)

IMPORTANT INFORMATION ABOUT FINTEPLA® FOR PATIENTS AND CAREGIVERS

Please read the Fintepla® Package Leaflet that comes with the medicine before taking Fintepla.

▼ This medicine is subject to additional monitoring.
This will allow quick identification of new safety information.
You can help by reporting any side effects that occur.
See the last page for information on reporting side effects.

This guide is intended for patients and caregivers.

Inspired by **patients.**
Driven by **science.**

INTRODUCTION

You or your child has been prescribed fenfluramine to treat seizures (fits) associated with a type of epilepsy called Dravet syndrome or Lennox-Gastaut syndrome. This guide contains information about the risks associated with fenfluramine and the tests and checks that are needed before, during and after stopping treatment with this medicine.

Your doctor will discuss this guide with you. Please use this discussion to ask any questions you may have. Please keep this guide in a safe place so that you can refer to it later.

WHAT ARE THE RISKS ASSOCIATED WITH FENFLURAMINE?

Two important risks associated with treatment with fenfluramine that require regular cardiac monitoring are:

- Development of a heart problem such as valvular heart disease (VHD)
- Development of pulmonary arterial hypertension (PAH, high pressure in the arteries of the lungs)

These are not the only risks associated with fenfluramine. Please refer to the Package Leaflet for further information.

What is valvular heart disease and why is there a risk when treated with fenfluramine?

Valvular heart disease is any disease that affects the valves of the heart. In the past, some adults who took fenfluramine developed valvular heart problems. These patients took much higher doses of fenfluramine than the dose prescribed to treat seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. Valvular heart disease was not observed in the clinical studies in Dravet syndrome and Lennox-Gastaut syndrome, but post-marketing data show that it can also occur with doses used to treat Dravet syndrome or Lennox-Gastaut syndrome.

What is pulmonary arterial hypertension and why is it a risk when treated with fenfluramine?

In pulmonary arterial hypertension (PAH), the pulmonary vessels (in the lungs) are narrowed, which increases the blood pressure in the pulmonary circulation. This form of high blood pressure is different from the common type of high blood pressure you may be aware of. Similar to valvular heart disease, some people have had pulmonary arterial hypertension in the past when they were treated with fenfluramine. In rare cases, it was severe or fatal. These patients took much higher doses of fenfluramine than the dose prescribed to treat seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. Pulmonary arterial hypertension was not reported in clinical studies in Dravet syndrome and Lennox-Gastaut syndrome, but it has been reported as a side effect in patients taking doses used to treat Dravet syndrome or Lennox-Gastaut syndrome.

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TESTS AND CHECKS

What tests are carried out before and during treatment with fenfluramine?

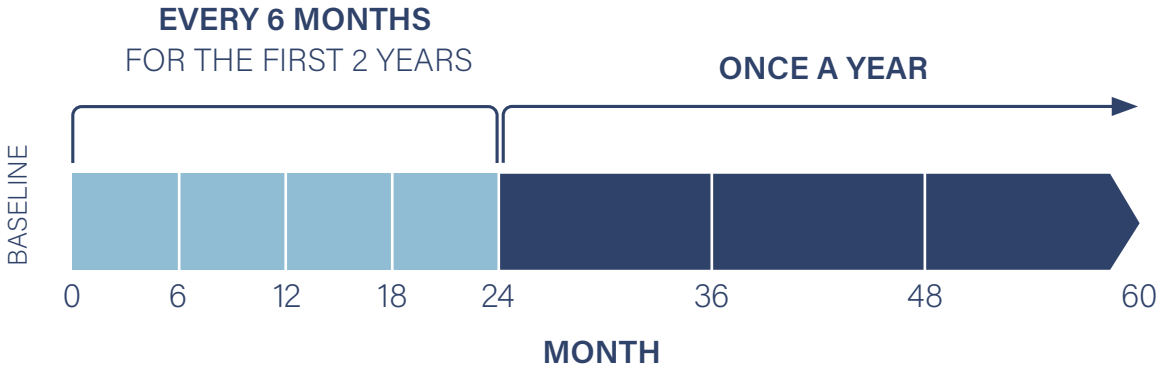
To ensure that you or your child does not have or does not develop a valvular heart problem or high pressure in the artery between the heart and the lungs (PAH), your doctor will carry out an examination of your heart, called an echocardiogram (so-called heart ECHO), before and during treatment with fenfluramine.

The heart ECHO is an external (non-invasive) procedure that uses ultrasound (high-frequency sound waves that are reflected by the heart as it beats) to create an image of the heart valves and calculate the pressure in the lung vessels. No radiation is used in this procedure.

How often is the heart ECHO repeated?

To ensure safe use of fenfluramine, it is important that patients with Dravet syndrome or Lennox- Gastaut syndrome receive a heart ECHO before starting treatment. The examination must be repeated every six months for the first two years and then once a year. If Fintepla treatment is stopped for any reason, you or your child will need to have an echocardiogram 3-6 months after the last dose.

Echocardiogram Monitoring Schedule



Doctor's appointment for your heart ECHOs:

Heart ECHO	Baseline examination	Month 6	Month 12	Month 18	Month 24	Month 36	Month 48	Month 60
Date								

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If a valvular heart problem or high pressure in the arteries of the lungs is detected during treatment with fenfluramine, your doctor may stop the medicine.
Regular heart checks will continue.

SAFETY REGISTRY

- A safety registry (which is required by the European Medicines Agency), has been set up in some EU Member States.
- It has been set up to collect data on the long-term safety of fenfluramine in the treatment of Dravet syndrome and Lennox-Gastaut syndrome.
- The studies' main focus is on cardiac monitoring and to improve the understanding of the safety of the medicine.

We would like to invite you to participate in these registries.

The success of registries depends on the largest possible number of participants.
Participation is voluntary and does not require any additional research, appointments or tests.
Please consult your doctor for information on participation.

REPORTING SIDE EFFECTS

If you experience any side effects, (this includes any side effects not listed in the Package Leaflet), contact your doctor, pharmacist or nurse. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

Further information can be found in the Package Leaflet provided in the package of the medicine.

RELATED DOCUMENT

Fintepla Package Leaflet fenfluramine 2.2 mg/ml oral solution can be found at https://www.hpra.ie/

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