

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**.

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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 during 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 of the possible risks associated with treatment with fenfluramine that require regular monitoring are:

- Development of a heart problem such as valvular heart disease
- Development of pulmonary arterial hypertension (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. The risk of developing valvular heart problems seemed to be related to the dose and the length of time they took the medicine.

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 normal high blood pressure. 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.

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TESTS AND CHECKS ?

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

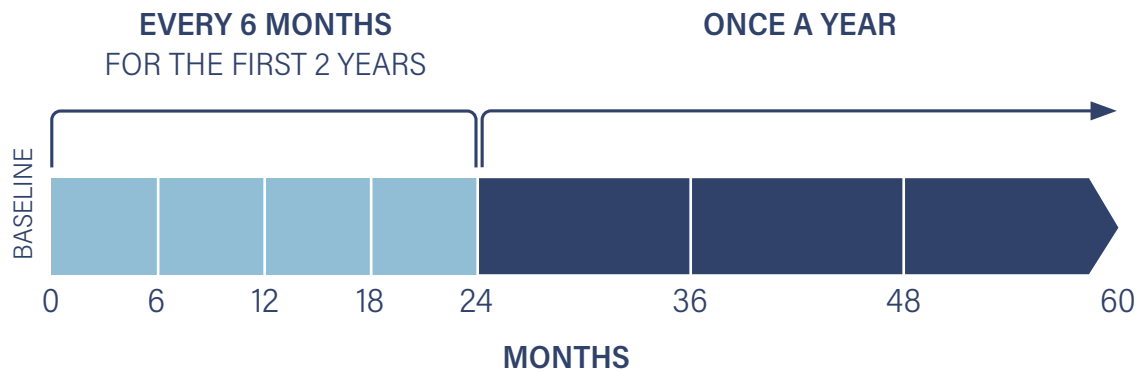
To ensure that you or your child does not have or does not develop a valvular heart problem or high pressure in the artery between the heart and the lungs (PAH), your doctor will carry out an examination of your heart, called an echocardiogram (so called **heart ECHO**), before and during treatment with 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 you or your child receive a heart ECHO before starting treatment. Once you or your child start taking fenfluramine, you will have a heart ECHO every six months for the first two years and then once a year:

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 treatment with fenfluramine is stopped, you or your child will need to have a heart ECHO six months after the last dose.

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.

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.ema.europa.eu/en/medicines/human/EPAR/fintepla#product-information-section>

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