If a valvular heart problem or pulmonary arterial hypertension is detected during treatment with fenfluramine, your doctor may stop the medicine. Regular heart checks will continue.

How will the risks of valvular heart disease and pulmonary arterial hypertension associated with fenfluramine be monitored in the future?

A registry has been set up in the UK and some EU Member States to collect data on the long-term safety of fenfluramine in the treatment of Dravet syndrome and Lennox-Gastaut syndrome, with a focus on valvular heart disease and pulmonary arterial hypertension and to improve the understanding of the safety of the medicine.

We would like to invite you to participate in this registry.

The success of the registry 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 notice side effects, (this includes any side-effects not listed in the Package Leaflet), contact your doctor or pharmacist.

You can also report side effects directly via Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

Appendix

Fintepla Package Leaflet fenfluramine 2.2 mg/ml oral solution

This guide is intended for patients and caregivers.

This guide was prepared in coordination with the MHRA. As an additional risk minimising measure, 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 IN GREAT BRITAIN

Please also refer to the Fintepla® Package Leaflet

▼ This medicine is subject to additional monitoring. This allows for the quick identification of new safety findings. 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 associated with 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 fenfluramine.

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.

Please also read the Package Leaflet that comes with the medicine for more information about fenfluramine.

WHAT ARE THE RISKS ASSOCIATED WITH FENFLURAMINE?

Two important risks associated with treatment with fenfluramine require cardiac monitoring:

- Development of valvular heart disease (VHD)
- Development of pulmonary arterial hypertension (PAH)

No patients developed valvular heart disease or pulmonary arterial hypertension in any of the clinical studies in Dravet syndrome or Lennox-Gastaut syndrome with Fintepla®, but post-marketing data show that pulmonary arterial hypertension can also occur with doses used to treat epilepsy. These are not the only risks associated with fenfluramine. Other risks are described in the Package Leaflet.

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 had 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. Pulmonary arterial hypertension was not observed in the clinical studies in Dravet syndrome and Lennox-Gastaut syndrome, but post-marketing data show that pulmonary arterial hypertension can also occur with doses used to treat epilepsy.

This guide is intended for patients and caregivers.

Fintepla® (fenfluramine) IMPORTANT INFORMATION FOR PATIENTS AND CAREGIVERS

TESTS AND CHECKS

What examinations and controls are carried out before and during treatment?

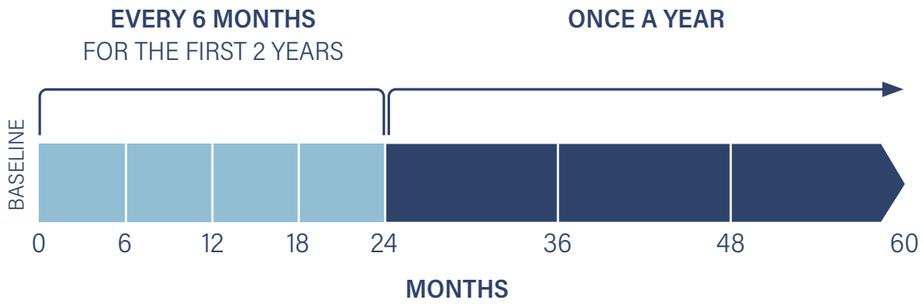
To ensure that you do not have or develop valvular heart problems or an unusually high pressure in the lung vessels, an examination of the heart, called an echocardiogram (so-called **heart ECHO**), is carried out before and during treatment.

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 pulmonary vessels. No radiation is used in this procedure.

How often is the heart ECHO repeated?

To ensure safe use of fenfluramine, it is important you 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, 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								

This guide is intended for patients and caregivers.