

This guide has been prepared in coordination with the Ministry of Health as an additional measure for the minimization of risks; it is designed to ensure that patients and their parents become familiar with the characteristics of Fintepla (fenfluramine), thereby reducing the potential risk of certain side effects.

## Fintepla<sup>®</sup> (fenfluramine)

# Important information about Fintepla for patients and their parents

Please read the Patient Information leaflet before use.

This medication is subject to additional monitoring. This enables the rapid identification of new safety findings.

You can help by reporting any side effects that occur. Please read the last page for information regarding reporting of side effects.

This guide is designed for patients and their parents.

## Introduction

Fintepla (fenfluramine) has been prescribed for you or for your child for the treatment of seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. This guide includes information about the risks associated with fenfluramine as well as the tests and follow ups required during the treatment with fenfluramine.

The attending physician will speak with you about this guide. Use the conversation to ask any questions you may have.

Keep this guide in a safe place so that you will be able to look at it later.

In addition, please read the Patient Information leaflet for more information about fenfluramine.

## What are the risks associated with fenfluramine?

There are two potential risks associated with fenfluramine treatment, which require regular follow up:

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

However, no patient has developed valvular heart disease or pulmonary arterial hypertension in any of the clinical trials conducted in patients with Dravet syndrome or Lennox-Gastaut syndrome under treatment with Fintepla. These are not the only risks associated with fenfluramine. Additional risks are described in the Patient Information leaflet.

### What is valvular heart disease, and why is there a risk during the treatment with fenfluramine?

Valvular heart disease is any disease that causes damage to the valves of the heart. In the past, some adults who took fenfluramine suffered from valvular heart disease. These patients took doses of fenfluramine that were much higher than the dose prescribed to treat seizures associated with Dravet syndrome or Lennox-Gastaut syndrome. It seemed that the risk of developing valvular heart problems was associated with the dose and with the duration of treatment with the medication.

### What is pulmonary arterial hypertension, and why is it a risk during the treatment with fenfluramine?

In pulmonary arterial hypertension (PAH), the pulmonary blood vessels (in the lungs) are narrowed, causing an increase of the blood pressure in the bloodstream in the lungs. This type of high blood pressure is different from regular high blood pressure. Similar to valvular heart disease, in the past, some people suffered from pulmonary arterial hypertension while being treated with fenfluramine. In rare cases, the pulmonary arterial hypertension was severe or led to death. These patients took doses of fenfluramine that were much higher than the dose prescribed to treat seizures associated with Dravet syndrome or Lennox-Gastaut syndrome.

## Tests and follow ups

### What tests and follow ups are performed before and during the treatment?

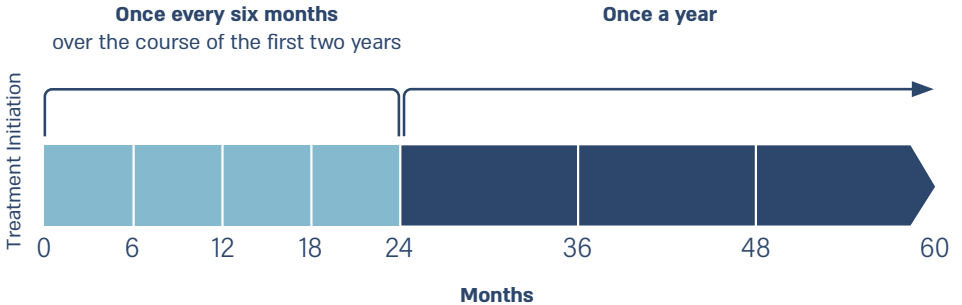
In order to ensure that patients with Dravet syndrome or Lennox-Gastaut syndrome are not suffering from valvular heart problems or from abnormally high blood pressure in the lungs' blood vessels, and that they are not developing such problems, an examination of the heart is performed, using a test called an echocardiogram (or heart echo), before and during the treatment.

The echocardiogram is an external (non-invasive) procedure that uses ultrasound (high frequency sound waves that are reflected back from the heart as it beats) to create a picture of the heart valves and calculate the pressure in the lungs' blood vessels. No radiation is used during this procedure.

### How often is a repeat echocardiogram performed?

In order to ensure the safe use of fenfluramine, it is important that patients with Dravet syndrome or Lennox-Gastaut syndrome will undergo an echocardiogram before initiating the treatment. The examination must be repeated once every six months over the course of the first two years, and then once a year:

### Schedule for Echocardiogram Follow Up



### Appointments scheduled with the attending physician for the performance of an echocardiogram examinations:

Echocardiogram	An examination at the initiation of the treatment	Month 6	Month 12	Month 12	Month 12	Month 12	Month 12	Month 12
Date								

If either a problem in the valves of the heart or pulmonary hypertension is detected during the treatment with fenfluramine, the attending physician may stop the treatment with the medication. Examinations of the heart will continue at regular intervals.

## Reporting of side effects

In case of any side effects (including any side effects not listed in the Patient Information leaflet), please refer to the attending physician or to the pharmacist.

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

Side effects can be reported to the Ministry of Health via the portal for the report of side effects on the homepage of the Ministry of Health: [www.health.gov.il](http://www.health.gov.il)  
Or by clicking on the link: <https://sideeffects.health.gov.il>

In addition, side effects can be reported to Medison Pharma Inc. by email at [pvisrael@medisonpharma.com](mailto:pvisrael@medisonpharma.com) or by fax at 03-9234218.

Please read the Patient Information leaflet before use.

This guide was approved and reviewed by the Ministry of Health in December 2023.