Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Fintepla
Solution (oral)

Active ingredient and quantity:
Each mL of solution contains 2.2 mg fenfluramine as fenfluramine hydrochloride

Inactive ingredients and allergens – see '**Important information about some of this medicine's ingredients**' in section 2, and section 6 '**Additional information**'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

In addition to the patient information leaflet, Fintepla also has a safety information guide for the patient and the patient's parents.
This guide contains important safety information that you need to know and that you should follow before you start and during treatment with Fintepla.
Read the safety information card for the patient and the patient's parents and the patient information leaflet before using this medicine.
Keep the card in case you need to read it again.

1. What is this medicine intended for?

Fintepla is indicated for the treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome as an add-on therapy to other antiepileptic medicines for patients 2 years of age and older.

Fintepla is not indicated for the treatment of obesity.
Therapeutic group - the medicine belongs to a class of medicines called antiepileptics.

2. Before using this medicine

Do not use this medicine if:

- You or your child are sensitive (allergic) to the active ingredient (**fenfluramine**) or to any of the other ingredients in this medicine (see section 6, **"Additional information"**).
- You or your child have a heart problem such as "valve disease" or "pulmonary arterial hypertension" (high pressure in the arteries of the lungs).
- You or your child have taken medicines called monoamine oxidase inhibitors in the last 2 weeks.

Special warnings about using this medicine
Fintepla is a preparation defined as a drug because it contains fenfluramine. It may cause dependence or may be misused. The preparation must be kept in a safe place to prevent misuse.

- Keep Fintepla in a safe place to protect it from theft.
  Selling or giving away Fintepla to others may cause damage and is against the law.
- Tell your doctor if you or your child have abused or developed a dependence on alcohol, prescription drugs, or illegal drugs.

Before using Fintepla, tell your doctor if:
- You or your child have high pressure in the eye (glaucoma).
- You or your child have had thoughts of harming or killing yourself.
- You or your child are being treated with a medicine called cyproheptadine, which is used to treat allergies or to improve appetite.
- You or your child are taking medicines that may increase the serotonin levels in your brain. These medicines in combination with Fintepla can cause **serotonin syndrome**, which is a life-threatening condition.
  - Medicines that can increase serotonin levels include:
    - Triptans (such as sumatriptan) - for treatment of migraines
    - Monoamine oxidase inhibitors (MAOI) - for treatment of depression
    - Selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitors (SNRI) medicines or tricyclic antidepressants- for treatment of depression and anxiety.
  - Signs of **serotonin syndrome** include:
    - Being agitated, hallucinations, fainting
    - Heart and circulation problems such as fast heartbeat, blood pressure going up and down, high body temperature, sweating
    - Twitching muscles and being uncoordinated
    - Nausea and diarrhoea

Contact your doctor straight away if you experience any of the serious side effects above.

Children
Fintepla is not intended for treatment of children below 2 years of age. There are no safety or efficiency data on the treatment of the product in children below 2 years of age.

Elderly
There are no data on the use of Fintepla in this population.

Tests and follow-up
While being treated with the medicine, your doctor must refer you for tests:
Heart - having an echocardiogram (ECHO). The doctor will check that the valves in the heart work properly and the pressure in the artery between the heart and lungs is not too high.
Once you or your child has started treatment, you should have an echocardiogram done every 6 months for the first 2 years and then once a year.
If Fintepla treatment is stopped, you or your child will need to have an echocardiogram 6 months after the last dose.

Weight - your doctor will check your weight before and during your treatment, as Fintepla can cause you to lose weight.

Drug interactions:
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. In particular if you or your child are taking or have recently taken one of the following medicines:

- Stiripentol - a medicine for epilepsy. This will require your Fintepla dose to be adjusted.
- Triptans, monoamine oxidase inhibitors (MAOI), selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs).
- Carbamazepine, primidone, rifampicin, phenobarbital and other barbiturates, phenytoin, and efavirenz - as your dose of Fintepla may need to be increased.

Fintepla can affect the way other medicines work. Also, other medicines can affect the way Fintepla works.
Fintepla can make you or your child feel sleepy. You or your child may be even more sleepy if you take anti-depressants.

Also speak with your doctor or pharmacist if you or your child smoke as the dose of Fintepla may need to be increased.

Using this medicine and food
Fintepla may be taken with or without food. If your stomach is sensitive, take the medicine with food.
Fintepla contains a very limited amount of carbohydrates and is compatible with a ketogenic diet.

Using this medicine and alcohol consumption
Consuming alcohol while taking Fintepla may lead to sleepiness.

Pregnancy, breast-feeding and fertility
Pregnancy: There are limited data on use during pregnancy. As a precautionary measure, it is preferable to avoid taking Fintepla during pregnancy.

Breast-feeding: It is unknown whether fenfluramine passes into breast milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to abstain from taking Fintepla, taking into account the benefit of breast-feeding and the importance of treatment with Fintepla.

Fertility: No effects of fenfluramine on human fertility up to clinical doses were noted, however, animal studies suggest that Fintepla may possibly harm female fertility.

Driving and using machines
Fintepla may cause sleepiness and fatigue. Therefore, it has a moderate effect on the ability to drive a car or operate machines. If you feel sleepy, you should refrain from driving or operating machines. If your child is treated with Fintepla and feels sleepy, they should refrain from riding a bicycle or other sports activity.

Important information about some of this medicine's ingredients
Fintepla contains sodium ethyl p-hydroxybenzoate (E 215) and sodium methyl phydroxybenzoate (E 219) - which may cause allergic reactions (possibly delayed)

Fintepla contains sulphur dioxide, (E220) which in rare cases may cause hypersensitivity reactions and bronchospasm.

Fintepla contains dextrose (glucose), which may be harmful to the teeth. If you or your child have an intolerance to some sugars, inform your doctor.

Fintepla contains sodium - 23 mg per 12 mL solution. At this concentration, the medicine is considered “sodium free”.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

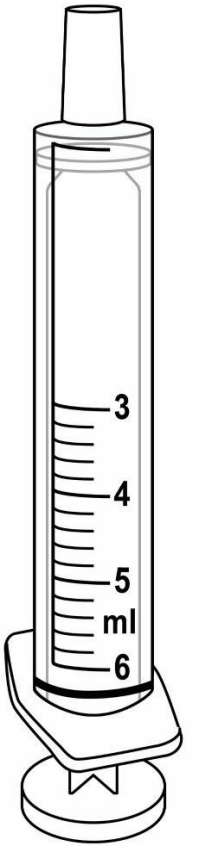
- Each dose will be defined as the number of mL to take.
- Take the medicine twice a day.
- Your doctor will start treatment with a low dose, which may be gradually increased according to the effect the medicine has on you or your child.
- The maximum dose is 6 mL twice a day.
- If you are taking stiripentol, the maximum dose you can take is 4 mL twice a day.

Do not exceed the recommended dose.

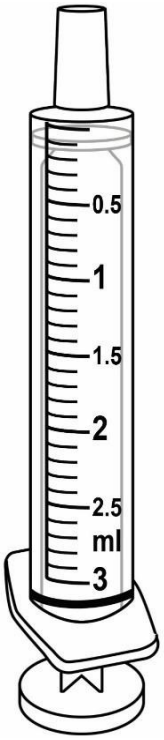
Method of administration

- Take the medicine with food or between meals.
- Fintepla is a solution, and it should be measured in the applicable oral syringe enclosed in the package.
- Use the green 3 mL syringe for doses up to 3.0 mL.
- Use the purple 6 mL syringe for doses between 3.2 mL and 6.0 mL.
- Fintepla is compatible for use with most enteral feeding tubes.
- To flush the feeding tube, fill the dosing syringe with water and flush the tube 3 times.

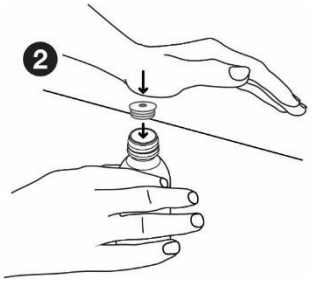
6 mL syringe - purple

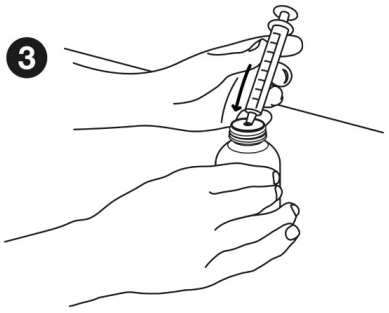
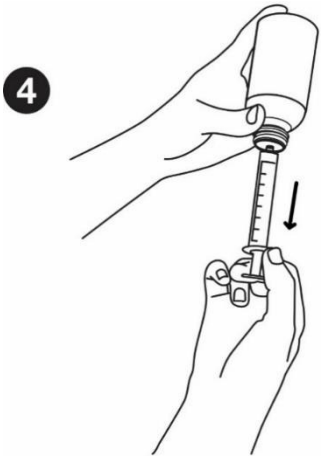
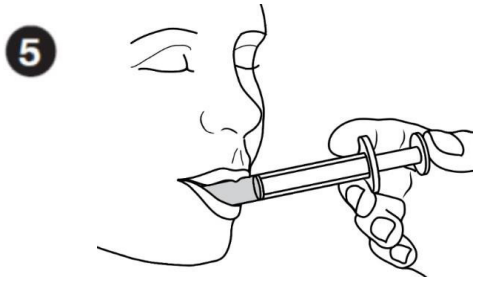
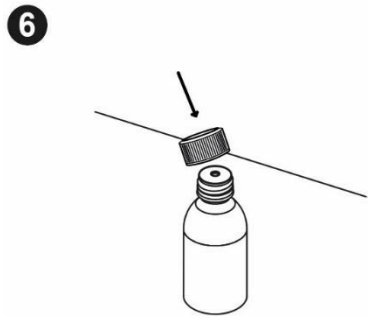


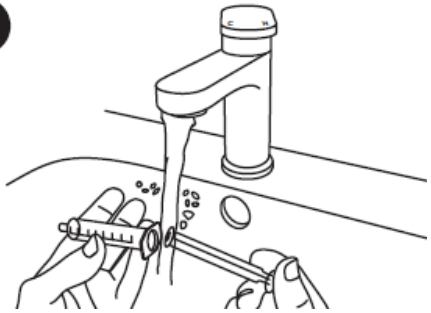
3 mL syringe - green



- Write on the carton the date you first opened the bottle.
- You must attach the bottle adaptor the first time you open the bottle.
- **Inserting the bottle adaptor - Figures 1 and 2:**
  - Wash and dry your hands.
  - Remove the bottle adaptor from its packaging.
  - Place the bottle on a flat and firm surface.
  - Open the bottle.
  - Push the bottle adaptor into the bottle.
  - Hold the bottle.
  - Line up the bottle adaptor with the upper part of the bottle.
  - Push the bottle adaptor into the bottle with your palm until the adaptor is flush with the top of the bottle.
  - Leave in the bottle adaptor after using the medicine.
  - Screw the bottle cap onto the bottle with the bottle adaptor left in.



• **Taking the medicine** • **Figure 3** o Before you measure out the dose, make sure the plunger is pushed all the way into the oral syringe. o Hold the bottle of medicine firmly on a hard, flat surface. o Push the tip of the oral syringe into the bottle adaptor until it cannot be pushed further.	
• **Figure 4** o Hold the oral syringe and bottle together and turn upside down. o Slowly pull the plunger to draw up the right dose. o Hold the oral syringe and bottle together and then turn over. o Holding the bottle firmly, gently pull the oral syringe out of the bottle adaptor.	
• **Figure 5** o Place the tip of the oral syringe against the inside of the patient's cheek. o Gently push the plunger until it is fully pressed. There will be a small volume left in the tip of the syringe. This is normal. o Do not squirt the medicine into the back of the throat as this may cause choking	
• **Figure 6** o Place the cap back on the bottle and turn until it stops. o Always leave the adaptor in place in the bottle.	

• **Cleaning the oral syringe - Figure 7** o Rinse the oral syringe with clean water and allow it to air dry after each use. o Rinse the inside of the syringe and the plunger. o Clean water can be pulled into the syringe with the plunger and pushed out several times to clean the syringe. o It is okay to separate the plunger from the syringe to rinse each part separately. o The syringe and plunger may be washed in a dishwasher. o The syringe and plunger must be completely dry before the next use.	7 

If you or your child has taken a higher dose, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
The following signs may appear: being agitated, sleepy or confused, being flushed or feeling hot, shivering and sweating.

If you forget to take the medicine
If you forget to take the medicine at the scheduled time, take the dose as soon as you remember, but if it is nearly time to take the next dose, do not take a double dose. **Skip the missed dose** and take your next dose at the usual time and consult your doctor. Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If your doctor decides to stop treatment with Fintepla, they will gradually lower the daily dose to reduce the risk of having a seizure and status epilepticus.
Six months after the last dose of Fintepla, you or your child will need to have an echocardiogram.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>
Like with all medicines, using Fintepla may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Serious side effects
Fintepla may cause serious side effects.
Contact your doctor immediately if you have any of these signs, which indicate serotonin syndrome:
- You are agitated, hallucinating (seeing things that aren't there) or passing out.

- Heart and circulation problems such as fast heartbeat, blood pressure going up and down, high body temperature, sweating.
- Twitching muscles and being uncoordinated.
- Feeling nauseous and diarrhoea.

Additional side effects:

Dravet syndrome

Very common side effects (may affect more than 1 in 10 patients)
- Upper respiratory tract infection
- Decreased appetite
- Drowsiness (somnolence)
- Diarrhoea
- Fever
- Feeling tired (fatigue), sleepy, or weak
- Decrease in blood sugar level
- Abnormal echocardiogram

Common side effects (may affect 1 in 10 patients)
- Bronchitis
- Abnormal behaviour
- Mood swings
- Aggression
- Agitation
- Insomnia
- Tremor in hands, arms or legs
- Problems coordinating movements, walking and balance (ataxia)
- Decreased muscle tone (hypotonia)
- Seizures
- Prolonged seizures (status epilepticus)
- Fatigue
- Weight decreased
- Constipation
- Excessive secretion of saliva (salivary hypersecretion)
- Blood prolactin increased

Side effects of unknown frequency (the frequency cannot be evaluated from the available data)
- Pulmonary arterial hypertension (PAH)

Lennox-Gastaut syndrome

Very common side effects (may affect more than 1 in 10 patients)
- Diarrhoea
- Vomiting
- Upper respiratory tract infection
- Feeling tired (fatigue), sleepy, or weak
- Drowsiness (somnolence)
- Decreased appetite

Common side effects (may affect 1 in 10 patients)
- Aggression
- Constipation
- Excessive secretion of saliva (salivary hypersecretion)
- Bronchitis
- Influenza
- Pneumonia
- Falls
- Weight decreased
- Seizures
- Prolonged seizures (status epilepticus)
- Lethargy
- Tremor in hands, arms, or legs
- Blood prolactin increased

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/label.
  The expiry date refers to the last day of that month.

Storage conditions:
- There are no special storage conditions. It is recommended to store at room temperature.
- Do not refrigerate. Do not freeze!
- Use within 3 months of first opening of the bottle and store at room temperature.

6. Additional information

In addition to the active ingredient, this medicine also contains:
- potassium citrate monohydrate
- citric acid monohydrate
- hydroxyethylcellulose
- (monosodium phosphate (E 339); Disodium phosphate (E 339)-pH stabilizers)
- sodium methyl para-hydroxybenzoate (E 219)
- sucralose (E 955)
- cherry flavouring powder:
  - dextrose (maize)
  - gum arabic/acacia gum (E414)
  - ethyl benzoate
  - sulphur dioxide (E 220)
  - natural flavouring preparations
  - natural flavouring substances

    - flavouring substances
    - maltodextrin (maize)
- sodium ethyl para-hydroxybenzoate (E 215)
- water for injections

What the medicine looks like and contents of the pack
Fintepla is a clear, colourless, cherry-flavoured slightly viscous solution.
Each carton contains:
- One bottle containing 60 mL, 120 mL, 250 mL or 360 mL of solution.
- Bottle adaptor.
- 2 3 mL dosing syringes with 0.1 mL graduations.
- 2 6 mL dosing syringes with 0.2 mL graduations.

Not all pack sizes may be marketed.

Registration holder's name and address: Medison Pharma Ltd., 10 Hashiloach, POB 7090*,* Petach Tikva.

Manufacturer's name and address: UCB Pharma S.A. Allée de la Recherche 60 B-1070 Bruxelles, Belgium

Revised in March 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
169-41-36976-99