Package leaflet: Information for the patient

Fintepla 2.2 mg/ml oral solution
fenfluramine

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you or your child may experience. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child starts taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- If you or your child experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fintepla is and what it is used for

Fintepla contains the active substance fenfluramine.

Fintepla is used to treat seizures (fits) in patients aged 2 years and over who have either a type of epilepsy called Dravet syndrome or one called Lennox-Gastaut syndrome. It can help to reduce the number and severity of seizures.

It is not completely known how Fintepla works. However, it is thought to work by increasing the activity in the brain of a natural substance called serotonin and the sigma 1 receptor, and this may reduce seizures.

2. What you need to know before you or your child takes Fintepla

Do not take Fintepla if:
- you or your child are allergic to fenfluramine or any of the other ingredients of this medicine (listed in section 6)
- 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.

Do not take Fintepla if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before taking Fintepla.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Fintepla if:
- you or your child have glaucoma
- you or your child have had thoughts about harming or killing yourself
- you or your child are taking a medicine called cyproheptadine, which is used to treat allergies or to improve appetite.

If any of the above applies to you or your child (or you are not sure), talk to your doctor, pharmacist or nurse before taking Fintepla.

Tests and checks
Before you or your child start taking Fintepla your doctor must check the heart with 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 taking Fintepla, you will have an echocardiogram check 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.

Your doctor should also check your weight before and during your treatment as Fintepla can cause you to lose weight.

'Serotonin syndrome'
Tell your doctor or pharmacist before taking Fintepla if you or your child are taking medicines which can increase the levels of serotonin in your brain. This is because taking these medicines and Fintepla can cause serotonin syndrome, which is a life-threatening condition. Medicines that can increase serotonin levels include:
- 'triptans' (such as sumatriptan) – used for migraine
- MAOI medicines – used for depression
- SSRI or SNRI medicines – used for depression and anxiety.

Look out for the signs of serotonin syndrome which include:
- being agitated, seeing things which are not there (hallucinations) 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 or being sick and diarrhoea.

Tell your doctor straight away if you notice any of the serious side effects above.

Other medicines and Fintepla
Tell your doctor or pharmacist if you or your child are taking, have recently taken, or might take any other medicines. This is because Fintepla can affect the way some other medicines work. Also, some 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 other medicines such as anti-depressants or alcohol at the same time as Fintepla.

In particular, tell your doctor or pharmacist if you or your child are taking, have recently taken, or might take:
- stiripentol, a medicine for epilepsy, as your dose of Fintepla may need to be reduced
- 'triptans', MAOI, SNRI or SSRI medicines – see above under 'Serotonin syndrome'
- carbamazepine, primidone, rifampicin, phenobarbital and other barbiturates, phenytoin, and efavirenz, as your dose of Fintepla may need to be increased.

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

Pregnancy and breast-feeding
If you or your child are pregnant, think you or your child might be pregnant, or are planning to have a baby or are breast-feeding, ask your doctor for advice before taking this medicine.

Driving and using machines
Talk to your doctor about driving, using machines, or if you or your child undertake activities such as cycling or other sports, because you or your child may feel sleepy after taking this medicine.

Fintepla contains sodium ethyl p-hydroxybenzoate (E 215) and sodium methyl p-hydroxybenzoate (E 219)
This may cause allergic reactions (possibly delayed).

Fintepla contains sulfur dioxide (E 220)
This may rarely cause hypersensitivity reactions and bronchospasm.

Fintepla contains glucose
This may be harmful to the teeth.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Fintepla contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 12 ml, that is to say essentially 'sodium-free'.

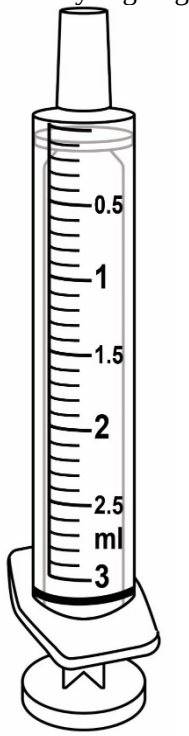
3. How to take Fintepla

Always take this medicine exactly as your doctor, pharmacist or nurse has told you. Check with them if you are not sure.

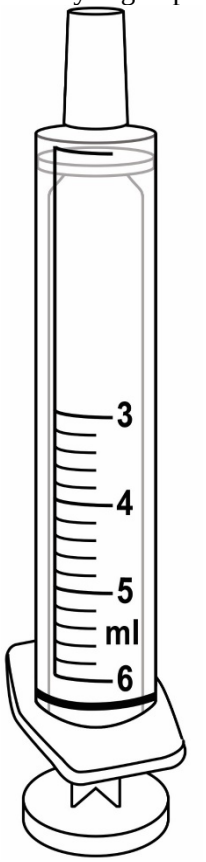
How much to take
- You will be told how many ml to take for each dose.
- Take the medicine twice a day.
- Your doctor will start you or your child on a low dose. This can then be gradually increased depending on how well the medicine works and how it affects you or your child.
- The maximum amount you can take is 6 ml twice a day.
- If you are taking stiripentol, the maximum amount you can take is 4 ml twice a day.
- Do not take more than the prescribed dose as it may cause serious side effects.

Taking this medicine
- Take this medicine by mouth.
- Take the medicine with food or between meals.
- Fintepla oral solution is compatible with a ketogenic diet.
- The medicine is a liquid. Use the oral syringes provided to measure your dose, as explained below.
- 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 oral solution is compatible with most enteral feeding tubes.
- To flush the feeding tube, fill the syringe used for dosing with water and flush the tube. Do this 3 times.

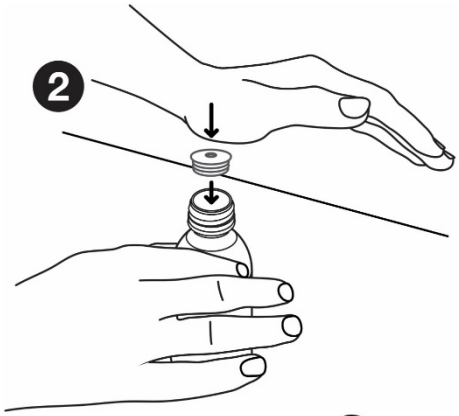
3 ml syringe - green



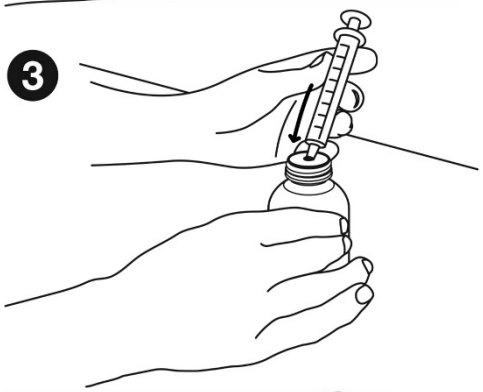
6 ml syringe - purple



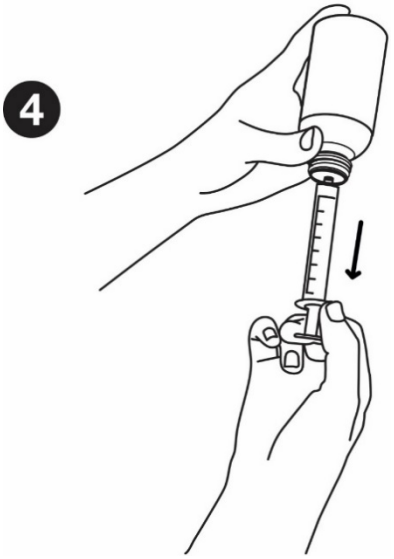
Write on the carton the date you first opened the bottle.
You must attach the bottle adaptor the first time you open the bottle. The following instructions tell you how to attach the adaptor.
Inserting the bottle adaptor:
When the bottle is first opened the bottle adaptor must be pushed into the bottle.
Wash and dry your hands.
Remove the bottle adaptor from its packaging.
Place the bottle on a flat, firm surface.
Open the bottle.



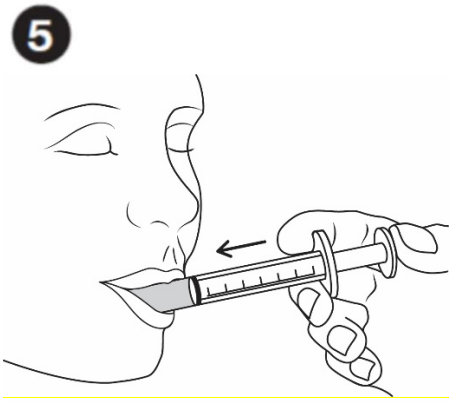
Hold the bottle firmly.
Line up the bottle adapter with the open top of the bottle.
Push the bottle adaptor into the bottle with your palm until the adaptor is flush with the top of the bottle.
Leave in the bottle adaptor after using the medicine.
Screw the bottle cap onto the bottle with the bottle adaptor left in.



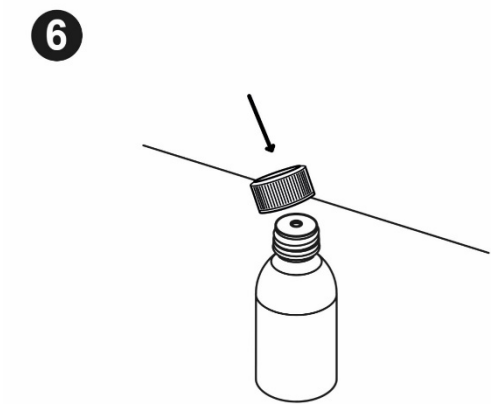
Taking the medicine:
Before you measure out the dose, make sure the plunger is pushed all the way into the oral syringe.
Hold the bottle of medicine firmly on a hard, flat surface.
Push the tip of the oral syringe into the bottle adaptor until it cannot be pushed further.



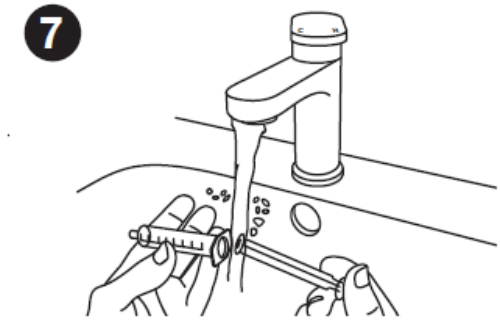
Hold the oral syringe and bottle together and turn upside down.
Slowly pull the plunger to draw up the right dose.
Hold the oral syringe and bottle together and then turn over.
Holding the bottle firmly, gently pull the oral syringe out of the bottle adaptor.



Place the tip of the oral syringe against the inside of the patient's cheek.
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.
Do not squirt the medicine into the back of the throat as this may cause choking.



Place the cap back on the bottle and turn until it stops.
Always leave the adaptor in place in the bottle.



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

If you or your child take more Fintepla than you or your child should
Talk to a doctor or go to a hospital straight away. Take the medicine bottle with you. The following effects may happen: being agitated, sleepy or confused, being flushed or hot, shivering and sweating.

If you or your child forget to take Fintepla
- Take it as soon as you remember it. However, if it is nearly time to take the next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten dose.

If you or your child stop taking Fintepla
Do not stop taking Fintepla without talking to your doctor. If your doctor decides to stop this medicine, the doctor will ask you or your child to slowly lower the amount taken each day. Slowly lowering the dose will 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dravet Syndrome
Very common: may affect more than 1 in 10 people
- Upper respiratory tract infection
- decreased appetite
- somnolence
- diarrhoea
- high temperature
- feeling tired, sleepy or weak
- lower blood sugar
- abnormal echocardiogram

Common: may affect up to 1 in 10 people
- bronchitis
- abnormal behaviour
- rapid mood changes
- aggression
- agitation
- insomnia
- trembling of the hands, arms or legs
- having problem with coordination of movements, walking and balance
- decreased muscle tone
- seizures
- long-lasting seizures (status epilepticus)
- lethargy
- weight loss
- constipation
- salivary hypersecretion
- increased blood prolactin

Not known (frequency cannot be estimated from the available data):
- high blood pressure in the arteries of the lungs (pulmonary arterial hypertension)

Lennox-Gastaut Syndrome
Very common: may affect more than 1 in 10 people
- diarrhoea
- vomiting
- upper respiratory tract infection
- feeling tired, sleepy or weak
- somnolence
- loss of appetite

Common: may affect up to 1 in 10 people
- aggression
- constipation
- salivary hypersecretion
- bronchitis
- influenza
- pneumonia
- falling

- weight loss
- seizures
- long-lasting seizures (status epilepticus)
- lethargy
- trembling of the hands, arms or legs
- increased blood prolactin

Tell your doctor, pharmacist or nurse if you notice any of the side effects listed above.

Reporting of side effects
If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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.

5. How to store Fintepla

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- Do not refrigerate or freeze.
- Use within 3 months of first opening the bottle.
- Wash the syringe after each use.
- If you lose or damage a syringe, or cannot read the dose markings on a syringe, use another oral syringe provided in your pack, or speak to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Fintepla contains
The active substance is called fenfluramine. Each ml contains 2.2 mg of fenfluramine (as fenfluramine hydrochloride).
The other ingredients are:
- Sodium ethyl para-hydroxybenzoate (E 215)
- Sodium methyl para-hydroxybenzoate (E 219)
- Sucralose (E 955)
- Hydroxyethylcellulose (E 1525)
- Monosodium phosphate (E 339)
- Disodium phosphate (E 339)
- Cherry flavouring powder:
    - Acacia (E 414)
    - Glucose (maize)
    - Ethyl benzoate
    - Natural flavouring preparations
    - Natural flavouring substances
    - Flavouring substances
    - Maltodextrin (maize)
    - Sulphur dioxide (E 220)

- Potassium citrate (E 332)
- Citric acid monohydrate (E 330)
- Water for injections

What Fintepla looks like and contents of the pack
- Fintepla oral solution is supplied as a clear, colourless, cherry-flavoured slightly viscous liquid.
- The solution is available in a white bottle with a child-resistant, tamper-evident cap.
- Each carton contains either:
    - Bottle containing 60 ml oral solution, a bottle adaptor, two 3 ml oral syringes with 0.1 ml graduations, and two 6 ml syringes with 0.2 ml graduations.
    - Bottle containing 120 ml oral solution, a bottle adaptor, two 3 ml oral syringes with 0.1 ml graduations, and two 6 ml syringes with 0.2 ml graduations.
    - Bottle containing 250 ml oral solution, a bottle adaptor, two 3 ml oral syringes with 0.1 ml graduations, and two 6 ml syringes with 0.2 ml graduations.
    - Bottle containing 360 ml oral solution, a bottle adaptor, two 3 ml oral syringes with 0.1 ml graduations, and two 6 ml syringes with 0.2 ml graduations.
- Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

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