

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Fintepla® ?

Fintepla® contains the active ingredient fenfluramine. Fenfluramine is used to treat seizures associated with 2 forms of childhood epilepsy: Dravet syndrome and Lennox-Gastaut syndrome.

For more information, see Section [1. Why am I using Fintepla®?](#) in the full CMI.

2. What should I know before I use Fintepla® ?

Do not use Fintepla® if you or your child have ever had an allergic reaction to fenfluramine or any of the ingredients listed at the end of the CMI, or if you or your child have a heart problem such as valve disease or pulmonary arterial hypertension, or if you or your child have taken medicines called monoamine oxidase inhibitors in the last 2 weeks.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Fintepla®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fintepla® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Fintepla® ?

- Fintepla® is an oral solution that is taken twice a day. The required dose will be calculated by your doctor based on your or your child's body weight. Starting at a low dose which may be gradually increased.

More instructions can be found in Section [4. How do I use Fintepla®?](#) in the full CMI.

5. What should I know while using Fintepla® ?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Fintepla®.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, taking the medicine bottle with you.
Things you should not do	<ul style="list-style-type: none">Do not use this medicine after the expiry date which is stated on the label and carton after EXP.
Looking after your medicine	<ul style="list-style-type: none">Keep this medicine out of the sight and reach of children.Store below 30°C. Do not refrigerate or freeze. Keep in the original carton to protect from light.

For more information, see Section [5. What should I know while using Fintepla®?](#) in the full CMI.

6. Are there any side effects?

Side effects that need serious medical attention include being agitated, having hallucinations or passing out, fast heartbeat, fever, twitching muscles and being uncoordinated, sleepy or confused, being flushed or hot, shivering or sweating, feeling sick or being sick and diarrhoea. These are symptoms of serotonin syndrome or of taking too much Fintepla®.

Common side effects include falling, diarrhoea, vomiting, weight loss, constipation, loss of appetite, high temperature, feeling tired, sleepy or weak, chest infection, bronchitis, influenza, ear infection, pneumonia, trembling of the hands, arms or legs, long-lasting seizures, irritability, lethargy, producing a lot of saliva, abnormal behaviour, rapid mood changes, aggression, agitation, insomnia, having problem with coordination of movements, walking and balance and decreased muscle tone.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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 may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: VALVULAR HEART DISEASE AND PULMONARY ARTERIAL HYPERTENSION

- There is an association between some serotonergic drugs including fenfluramine (the active ingredient in Fintepla), and problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries of the lungs (pulmonary arterial hypertension).
- Echocardiogram assessments are required before, during and after treatment with Fintepla.

Fintepla[®] Active ingredient(s): *fenfluramine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fintepla[®]. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fintepla[®].**

Where to find information in this leaflet:

1. Why am I using Fintepla[®] ?
2. What should I know before I use Fintepla[®] ?
3. What if I am taking other medicines?
4. How do I use Fintepla[®] ?
5. What should I know while using Fintepla[®] ?
6. Are there any side effects?
7. Product details

1. Why am I using Fintepla[®]

Fintepla[®] contains the active ingredient fenfluramine. Fenfluramine is thought to work by increasing the activity in the brain of a natural substance called serotonin and the sigma-1 receptor.

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

2. What should I know before I use Fintepla[®] ?

Warnings

Do not use Fintepla[®] if:

- You or your child are allergic to fenfluramine or any of the other ingredients listed at the end of this leaflet.
- You or your child have problems with the valves in the heart (valvular heart disease) and high blood pressure in the arteries in the lungs (pulmonary arterial hypertension)..

- You or your child have taken medicines called monoamine oxidase inhibitors (MAOIs) in the last 2 weeks.

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

Check with your doctor if you or your child:

- have glaucoma,
- have had thoughts about harming or killing yourself,
- are taking a medicine called cyproheptadine, which is used to treat allergies or improve appetites.
- have heart problems.
- have or have had weight loss.
- have or have had depression or mood problems.
- have kidney problems, have liver problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Tests and Checks

Before you or your child start taking Fintepla[®] your doctor must check the heart with an echocardiogram. 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 (such as phenelzine and tranylcypromine) – used for depression,
- Medicines called selective serotonin uptake inhibitors (SSRI) e.g., sertraline, citalopram, fluoxetine etc. or serotonin-noradrenaline reuptake inhibitors (SNRI) e.g., venlafaxine, desvenlafaxine and duloxetine – 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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Fintepla is not recommended for use during pregnancy.

Children

Fintepla® is not recommended for children under 2 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Other Medicines

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fintepla®.

4. How do I use Fintepla® ?

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

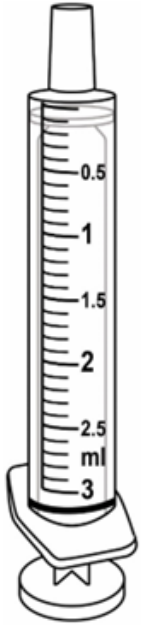
How much to take

- You will be told how many milliliters (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.

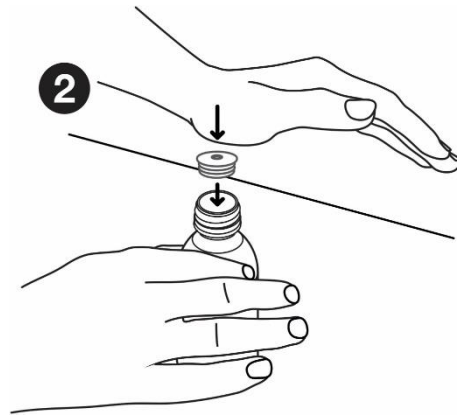
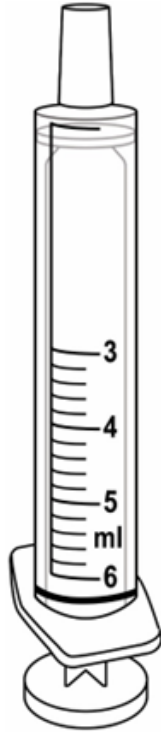
How to take Fintepla®

- 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.

3mL syringe – green



6mL syringe – purple



Hold the bottle firmly.

Line up the bottle adaptor 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.



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:

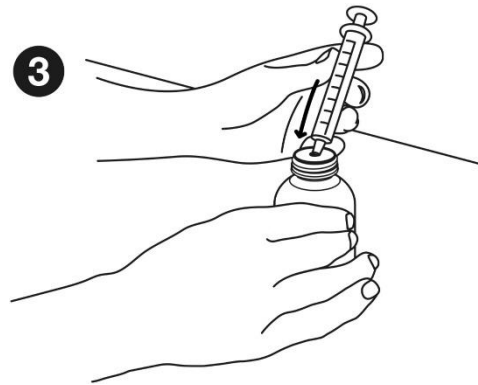
When the bottle is first opened the bottle adaptor must be pushed into the bottle.

Wash and dry your hands.

Remove the bottle adaptor from its packaging.

Place the bottle on a flat, firm surface.

Open the bottle.



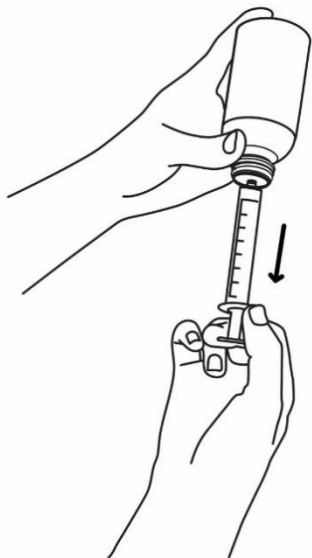
Taking the medicine:

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.

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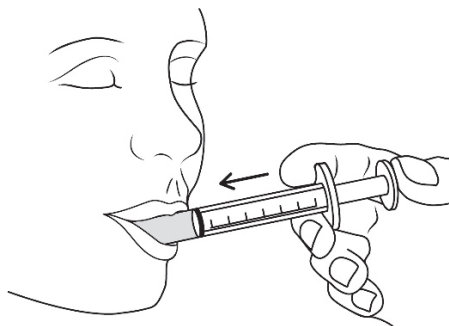
Hold the oral syringe and bottle together and turn upside down.

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.

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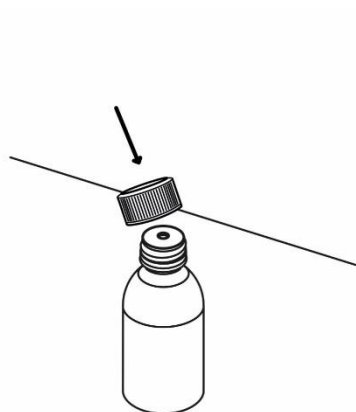


Place the tip of the oral syringe against the inside of the patient's cheek.

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.

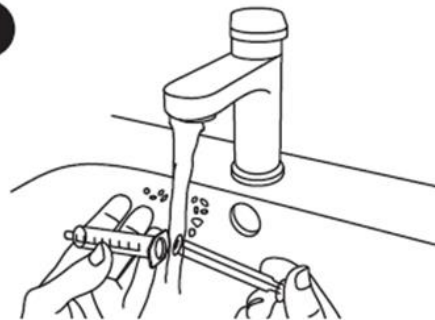
6



Place the cap back on the bottle and turn until it stops.

Always leave the adaptor in place in the bottle.

7



Cleaning the syringe:

Rinse the oral syringe with cold water and allow it to air dry after each use.

- Rinse the inside of the syringe and the plunger.
- Cold 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.
- Do not use detergent to clean the syringe and plunger
- Do not clean the syringe and plunger in a dishwasher.

The syringe and plunger must be completely dry before the next use.

If you forget to take Fintepla®

Take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for the dose you missed.

If you or your child take more Fintepla® than you or your child should

You should immediately:

- Phone the Poisons Information Centre (by calling 13 11 26), or
- Contact your doctor, or
- Go to the Emergency Department at your nearest hospital. Take the medicine bottle with you.

You should do this even if there are no signs of discomfort or poisoning.

The following effects may happen being agitated, sleepy or confused, being flushed or hot, shivering and sweating.

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.

5. What should I know while using Fintepla® ?

Remind any doctor, dentist or pharmacist you visit that you or your child is taking Fintepla®.

Things you should not do:

Use the medicine if:

- the expiration date on the packaging has passed (the expiry date refers to the last day of that month),
- the carton seals have been broken, or
- it is more than 3 months since the bottle was first opened.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fintepla® affects you.

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.

Looking after your medicine

- Store Fintepla below 30°C. Do not refrigerate or freeze.
- Keep the bottle in the outer carton in order to protect it from light.
- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Discard after the expiry date, or if it is more than 3 months since the bottle was first opened.

Getting rid of any unwanted medicine

Do not use this medicine after the expiry date.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are mild and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Infection:</p> <ul style="list-style-type: none"> • High temperature (fever) • Chest infection • Bronchitis • Influenza • Ear infection (otitis media) • Pneumonia <p>Stomach and gut:</p> <ul style="list-style-type: none"> • Diarrhoea • Vomiting • Loss of appetite • Weight loss • Constipation <p>General:</p> <ul style="list-style-type: none"> • Falling • Feeling tired, sleepy or weak • Trembling of the hands, arms or legs • Long-lasting seizures (status epilepticus) • Irritability • Lethargy • Producing a lot of saliva • Abnormal behaviour • Rapid mood changes • Aggression • Agitation • Insomnia • Having problem with coordination of movements, walking and balance • Decreased muscle tone 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Serotonin syndrome:</p> <ul style="list-style-type: none"> • 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 <p>Allergic reaction:</p> <ul style="list-style-type: none"> • difficulty breathing or swallowing • low blood pressure, which can make you dizzy or light-headed 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> swelling of the face, lips, tongue or throat severe itching of the skin, with a red rash or raised bumps. <p>Valvular heart disease or pulmonary arterial hypertension:</p> <ul style="list-style-type: none"> shortness of breath tiredness or weakness, especially with increased activity lightheadedness or fainting swollen ankles or feet chest pain sensations of a rapid, fluttering heartbeat (palpitations) irregular pulse bluish colour to your lips and skin (cyanosis) 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects that you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Fintepla® contains

Active ingredient (main ingredient)	Fenfluramine (as hydrochloride)
Other ingredients (Inactive ingredients)	<ul style="list-style-type: none"> Sodium ethyl hydroxybenzoate (E 215) Sodium methyl hydroxybenzoate (E 219) Sucralose (E 955) Hyetellose (E 1525) Monosodium phosphate (E 339) Disodium phosphate (E 339) Cherry flavouring powder: <ul style="list-style-type: none"> Acacia (E 414) Glucose (maize) Ethyl benzoate Natural flavouring preparations

	<ul style="list-style-type: none"> Natural flavouring substances Flavouring substances Maltodextrin (maize) Sulphur dioxide (E 220) Potassium citrate (E 332) Citric acid monohydrate (E 330) Water
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Do not take this medicine if you are allergic to any of these ingredients.

What Fintepla® looks like

Fintepla® oral solution is a clear, colourless, cherry-flavored slightly viscous liquid. The solution is provided in a white bottle with a child-resistant and tamper evident cap.

Each pack contains a bottle adapter, two green 3 mL oral syringes with 0.1 mL graduations, and two purple 6 mL syringes with 0.2 mL graduations and the medicine bottle, either:

- A bottle containing 60 mL oral solution (Aust R 429413),
- A bottle containing 120 mL oral solution (Aust R 429413),
- A bottle containing 250 mL oral solution (Aust R 429413), or
- A bottle containing 360 mL oral solution (Aust R 429413).

Who distributes Fintepla®

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