

# ORION PHENOBARBITAL ELIXIR

## 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.

### 1. Why am I using Orion Phenobarbital Elixir?

Orion Phenobarbital Elixir contains the active ingredient phenobarbital. Orion Phenobarbital Elixir is used to treat people with epilepsy.

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

### 2. What should I know before I use Orion Phenobarbital Elixir?

Do not use if you are allergic, or have ever had any unusual or allergic reactions to phenobarbital (or barbiturates), or any of the ingredients listed at the end of this leaflet.

Talk to your doctor or pharmacist 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 Orion Phenobarbital Elixir?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Orion Phenobarbital Elixir 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 Orion Phenobarbital Elixir?

Take this medicine as directed by your doctor.

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

### 5. What should I know while using Orion Phenobarbital Elixir?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Orion Phenobarbital Elixir.</li><li>• Tell your doctor if you become pregnant while taking this medicine.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use any other medicines while taking Orion Phenobarbital Elixir without first telling your doctor.</li><li>• Do not stop taking the medicine without talking to your doctor</li><li>• Do not give your Orion Phenobarbital Elixir to anyone else.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate machinery until you know how Orion Phenobarbital Elixir affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while taking Orion Phenobarbital Elixir. Combining this medicine with alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with this medicine.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Orion Phenobarbital Elixir below 30°C in a cool dry place, protected from moisture, heat or sunlight.</li></ul>

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

### 6. Are there any side effects?

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.

# ORION PHENOBARBITAL ELIXIR

Active ingredient(s): *Phenobarbital 15mg in 5mL*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Orion Phenobarbital Elixir. **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 Orion Phenobarbital Elixir.**

**Where to find information in this leaflet:**

- [1. Why am I using Orion Phenobarbital Elixir?](#)
- [2. What should I know before I use Orion Phenobarbital Elixir?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Orion Phenobarbital Elixir?](#)
- [5. What should I know while using Orion Phenobarbital Elixir?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Orion Phenobarbital Elixir?

**Orion Phenobarbital Elixir contains the active ingredient phenobarbital.** Orion Phenobarbital Elixir is a barbiturate which belongs to a group of medicines called central nervous system depressants (medicines that cause drowsiness).

**Orion Phenobarbital Elixir is used to treat people with epilepsy.** Your doctor, however, may have prescribed Orion Phenobarbital Elixir for another purpose. Ask your doctor if you have any questions about why Orion Phenobarbital Elixir has been prescribed for you.

## 2. What should I know before I use Orion Phenobarbital Elixir?

### Warnings

**Do not use Orion Phenobarbital Elixir if:**

- you are allergic, or have ever had any unusual or allergic reactions to phenobarbital (or barbiturates), or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include red itchy skin rashes, difficulty breathing, hay fever, swelling of the face, lips, tongue or other parts of the body.

Always check the ingredients to make sure you can use this medicine.

- you have, or have had any of the following medical conditions:**
  - Porphyria, a rare blood pigment disorder
  - Anaemia, a condition of the blood with a reduced number of red blood cells
  - Lung, liver or kidney problems
  - Sleep apnoea
  - Uncontrolled diabetes
  - Severe depression or suicidal tendencies
  - Alcoholism or drug dependence
  - Uncontrolled pain

### Check with your doctor if you:

- If you have any other medical conditions/health problems, including:
  - Blood problems
  - Short or long-term pain
- have any other medical conditions
- take any medicines or treatment for any other condition
- If you are or may become pregnant
- If you are breast feeding

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?](#)

### Pregnancy and breastfeeding

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

Barbiturates have been shown to increase the chance of birth defects in humans. However, this medicine may be needed in serious illnesses or other situations that threaten the mother's life.

If you plan a pregnancy, you should take a folic acid supplement (5mg) four weeks before you get pregnant and take the folic acid (5mg) for 12 weeks after you fall pregnant. While pregnant you should have additional ultrasound checks, please discuss this with your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Orion Phenobarbital Elixir passes into breast milk and can affect the breastfed baby.

Phenobarbital is thus not recommended in breastfeeding mothers.

### Use in the Elderly:

Confusion, mental depression and unusual excitement may occur in the elderly who are usually more sensitive than younger adults to the effects of barbiturates. Also,

elderly patients are more likely to have less effective kidney or liver function due to age. This may increase the risk of side effects.

You should discuss with your doctor how much Orion Phenobarbital Elixir to take.

### Use in the Children:

Excitement may occur in children who are more sensitive to the effects of barbiturates than adults.

Orion Phenobarbital Elixir should not be given to unusually overactive children.

## 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.

### Some medicines may interfere with Orion Phenobarbital Elixir and affect how it works.

It is especially important to tell your doctor if you are taking any of the following medicines and to talk to him before you take them for the first time:

- Other medications used to treat epilepsy
- Anticoagulants, medicines used to treat clots e.g. warfarin
- Painkillers, paracetamol and stronger narcotic medicines
- Anaesthetic agents
- Antidepressants, medicines used to treat depression
- Antipsychotics, medicines used to treat certain mental and emotional conditions
- Stimulants such as amphetamines, dexamphetamines
- Immunosuppressive medicines used to lower your body's resistance to disease e.g. Cyclosporin, tacrolimus
- Antibiotics, antivirals and antifungals, medicines used to treat infections including AIDS
- Medicines used to treat heart conditions, irregular heartbeats, high blood pressure, angina
- Disulfiram, a medicine used to treat alcoholism
- Urinary alkalisers
- Carbonic anhydrase inhibitors e.g. acetazolamide, medicines used to treat glaucoma, oedema (fluid build-up)
- Antihistamines, medicines used to treat or prevent the treatment of allergy
- Theophylline, a medicine used to treat asthma
- Corticosteroids such as prednisolone, cortisone
- Oestrogens, hormones used in oral contraceptive pills and in hormone replacement therapy

- St John's Wort (*Hypericum perforatum*)

These medicines may be affected by Orion Phenobarbital Elixir or affect how well it works. You may need different amounts of medicine, or may need to take different medicine. Your doctor or pharmacist will advise you.

Your doctor may advise you to use an additional form of contraception while taking Orion Phenobarbital Elixir.

If you are going to have a flu vaccine, tell your doctor that you are taking Orion Phenobarbital Elixir. Your doctor may need to adjust your dose of Orion Phenobarbital Elixir.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Orion Phenobarbital Elixir.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Orion Phenobarbital Elixir.**

## 4. How do I use Orion Phenobarbital Elixir?

### How much to take / use

- Take this medicine as directed by your doctor.
- Your doctor will decide on the best dose of Orion Phenobarbital Elixir for you. It will depend on your age, weight and illness.
- Do not take more of it or take it more often.
- The number of doses you take each day and the time between each dose will depend on your medical problem.

### If you forget to use Orion Phenobarbital Elixir

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

Otherwise take it as soon as you remember, and then go back to taking it as you would normally.

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

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

### If you use too much Orion Phenobarbital Elixir

If you think that you have used too much Orion Phenobarbital Elixir, you may need urgent medical attention.

#### 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.

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

Taking an overdose of Orion Phenobarbital Elixir or taking alcohol or medicines such as sleeping tablets, sedatives,

tranquillizers and strong painkillers with Orion Phenobarbital Elixir may lead to unconsciousness.

Some signs of overdose are severe drowsiness, dizziness, confusion, weakness, nausea, vomiting, trouble breathing, slurred speech and staggering.

## 5. What should I know while using Orion Phenobarbital Elixir?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Orion Phenobarbital Elixir.

If you are taking this medicine regularly for a long time your doctor should check your progress at regular intervals.

Orion Phenobarbital Elixir may be habit-forming if taken in high doses for a long period of time. Talk to your doctor or pharmacist if you are concerned about this.

Be sure to keep all your doctor's appointments so that your progress can be checked. Your doctor will check your progress and may want to take some tests from time to time to help prevent unwanted side effects.

If you have to take any medical tests while you are taking Orion Phenobarbital Elixir tell your doctor that you are taking this medicine as it may affect the results of some tests.

Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

### Things you should not do

Do not take it for longer than told to by your doctor. If taken too much it may become habit forming.

Do not stop taking the medicine without talking to your doctor, it must be taken regularly to control your epilepsy, do not miss any doses.

Stopping Orion Phenobarbital Elixir suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you stop taking it completely.

Do not give your Orion Phenobarbital Elixir to anyone else. Taking barbiturates may lead to dependence on the medicine.

### Driving or using machines

Orion Phenobarbital Elixir may cause drowsiness.

**You should be sure how you react to Orion Phenobarbital Elixir before you drive your car or operate machinery or do anything else that could be dangerous if you are dizzy or not alert.**

## Drinking alcohol

### Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while taking Orion Phenobarbital Elixir. Combining this medicine with alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with this medicine.

### Looking after your medicine

#### Keep out of reach of children since overdose is especially dangerous in children.

A locked cupboard at least one-and a-half metres above the ground is a good place to store medicines.

#### Store Orion Phenobarbital Elixir below 30°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

### Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date. If you take it after the expiry date has passed, it may have no effect at all, or worse, an entirely unexpected effect.

Do not take Orion Phenobarbital Elixir if the packaging is torn or shows signs of tampering.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor 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
<ul style="list-style-type: none"><li>• Drowsiness</li><li>• Rapid heartbeat</li><li>• Nausea (feeling sick)</li><li>• Constipation</li><li>• Dizziness</li><li>• Lethargy</li><li>• Vomiting</li><li>• Skin rashes</li><li>• Sweating</li><li>• Dry mouth</li><li>• Confusion</li><li>• Faintness</li><li>• Irritability</li><li>• Restlessness</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<ul style="list-style-type: none"> <li>• Mood changes</li> <li>• Hyperexcitability</li> <li>• Hangover</li> <li>• Sleep disturbances</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Sore throat</li> <li>• Fever</li> <li>• Easy or unusual bleeding or bruising under the skin</li> <li>• Nosebleed</li> <li>• Other signs of infections e.g. swollen glands, mouth ulcers</li> <li>• Sudden signs of allergy (red itchy skin rashes, difficulty breathing, hay fever, swelling of the face, lips, tongue or other parts of the body)</li> <li>• Severe skin rash, itching, hives, blisters or peeling skin</li> </ul>	<p><b>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.</b></p>

**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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://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 Orion Phenobarbital Elixir contains

<b>Active ingredient (main ingredient)</b>	Phenobarbital
<b>Other ingredients (inactive ingredients)</b>	Ethanol Glycerol Sorbitol Water

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Orion Phenobarbital Elixir looks like

Orion Phenobarbital Elixir is an elixir flavoured with butterscotch flavour.

Australian Registration Number AUST R 21187

### Who distributes Orion Phenobarbital Elixir

Orion Laboratories Pty Ltd T/A Evaris Pharma

Perrigo Australia

25 – 29 Delawney Street

Balcatta WA 6021

Australia

[www.evarispharma.com](http://www.evarispharma.com)

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