

ORION PHENOBARBITAL ELIXIR

Phenobarbital 15mg in 5mL

Consumer Medicine Information

Important information about your medicine

This medicine the doctor has prescribed for you is called Orion Phenobarbital Elixir.

The information in this leaflet will answer some of the questions you may have about Orion Phenobarbital Elixir. This leaflet does not tell you everything. Your doctor or pharmacist has been provided with full information and can answer any questions you may have.

This leaflet does not replace the advice given to you by your doctor. Talk to your doctor or pharmacist.

You should read this leaflet before taking Orion Phenobarbital Elixir and keep it in a safe place to refer to later.

What Orion Phenobarbital Elixir is used for

Orion Phenobarbital Elixir is used to treat people with epilepsy. It is a barbiturate which belongs to a group of medicines called central nervous system depressants (medicines that cause drowsiness). 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.

Before taking this medicine

When deciding to take a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For barbiturates the following should be considered:

Allergies: Tell your doctor if you have ever had any unusual or allergic reactions to phenobarbital or barbiturates, or any of the ingredients in Orion Phenobarbital Elixir (see **Product Description**). 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. Tell your doctor if you are allergic to any other substances such as food, preservatives or dyes.

Medical Conditions: Do not take Orion Phenobarbital Elixir if 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

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

Do not take Orion Phenobarbital Elixir after the expiry date printed on the bottle. 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.

Pregnancy: 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 mothers life.

Discuss this with your doctor if you are pregnant or plan a pregnancy.

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.

Breastfeeding: Discuss with your doctor if you are breastfeeding or plan to breastfeed. Orion Phenobarbital Elixir passes into breast milk and can affect the breastfed baby. Phenobarbital is thus not recommended in breastfeeding mothers.

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

Older Adults: 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.

Before you take Orion Phenobarbital Elixir for the first time you should tell your doctor

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

Precautions while taking this medicine

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

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

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.

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 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.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Orion Phenobarbital Elixir. If you are about to be started on any new medicine, tell your doctor, dentist or pharmacists that you are taking this medicine.

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.

Driving or operating machinery while taking Orion Phenobarbital Elixir

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.

How to take Orion Phenobarbital Elixir

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

The number of doses you take each day and the time between each dose will depend on your medical problem.

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.

If you forget to take it

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 that you missed.

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

Taking Orion Phenobarbital Elixir with other medicines

Some medicines can affect the way Orion Phenobarbital Elixir works. It is important that you tell your doctor before taking any other medicine even those bought without a prescription from your pharmacy, supermarket or health food shop.

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 eg 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 eg Cyclosporin, tacrolimus
- Antibiotics, antivirals and antifungals, medicines used to treat infections including AIDS
- Medicines used to treat heart conditions, irregular heart beats, high blood pressure, angina
- Disulfram, a medicine used to treat alcoholism
- Urinary alkalisers
- Carbonic anhydrase inhibitors eg 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.

Side Effects

All medicines including Orion Phenobarbital Elixir can cause unwanted effects.

The most common side effect with Orion Phenobarbital Elixir is likely to be drowsiness.

Tell your doctor if you notice any of the following and they worry you:

- Rapid heartbeat
- Nausea (feeling sick)
- Constipation
- Dizziness
- Lethargy
- Vomiting
- Skin rashes
- Sweating
- Dry mouth
- Confusion
- Faintness
- Irritability
- Restlessness
- Mood changes
- Drowsiness
- Hyperexcitability
- Hangover
- Sleep disturbances

Tell your doctor immediately or go to the Accident and Emergency at your nearest hospital if you notice any of the following:

- Sore throat
- Fever
- Easy or unusual bleeding or bruising under the skin
- Nosebleed
- Other signs of infections eg swollen glands, mouth ulcers
- Sudden signs of allergy (listed on page 1)
- Severe skin rash, itching, hives, blisters or peeling skin

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you

notice anything that is making you feel unwell.

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

Overdose

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Orion Phenobarbital Elixir. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

Other information about Orion Phenobarbital Elixir

Do not give your Orion Phenobarbital Elixir to anyone else.

Taking barbiturates may lead to dependence on the medicine.

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

Storing Orion Phenobarbital Elixir

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

Do not keep out of date medicine.

Store Orion Phenobarbital Elixir
below 30°C.

Product description

Orion Phenobarbital Elixir is an elixir flavoured with butterscotch flavour, it also contains phenobarbital, ethanol, glycerol, sorbitol and water.

Sponsor

This product is supplied by

Orion Laboratories Pty Ltd T/A
Perrigo Australia
25 - 29 Delawney Street
Balcatta WA 6021
Phone: 1800 805 546

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END OF CONSUMER MEDICINE
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