

PATIENT INFORMATION LEAFLET

Phenobarbital Thornton & Ross 15mg/5ml Elixir

Important things you need to know:

- Phenobarbital Elixir is prescribed to treat epilepsy.
- Take Phenobarbital Elixir regularly to get the most benefit. Do not stop taking the medicine without talking to your doctor first. Stopping the medicine abruptly can cause problems.
- Phenobarbital can cause side effects, although most people do not have serious problems - see section 4 for details. If you have fever, skin rashes or skin yellowing, mouth ulcers, bruising or bleeding, see your doctor immediately.
- Some side effects may occur early on in treatment. These often disappear after a few days as your body gets used to the drug.
- Taking other medicines including other anti-epilepsy drugs may sometimes cause problems, see section 2 for details. Check with your doctor before taking any other medicines.
- If you might become pregnant while taking Phenobarbital it is important that you talk to your doctor about this.

Now read the rest of the leaflet before you use this medicine. It includes other information which might be especially important for you.

Keep this leaflet. You may need to read it again.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What the medicine is for

Phenobarbital Elixir is a barbiturate drug, taken by mouth to treat epilepsy. It can be taken by adults and children.

2. Before you use this medicine

Take special care with Phenobarbital

A small number of people being treated with anti-epileptics such as Phenobarbital have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Phenobarbital Elixir contains a significant amount of alcohol. **(See Important information about some of the ingredients of this medicine).**

You must avoid other sources of alcohol while using this medicine.

If you are alcoholic, or have a history of alcohol abuse there may be a more appropriate medicine to treat your epilepsy. Tell your doctor or pharmacist if this applies to you.

Take special care if you have liver disease or if this medicine is prescribed for a baby or child.

If you have severe pain, Phenobarbital may not produce a calming action, and may cause wakefulness, excitement and delirium, unless taken with a painkiller.

Young, elderly, depressed, feeble or weak people need to take special care when using this medicine, as they can react differently to it. Talk to your doctor about this if it applies to you, or if you have any concerns about your reaction to the medicine.

Prolonged use may lead to dependence

If you are concerned that you are becoming addicted to this medicine, talk to your doctor or pharmacist as soon as possible, but do not stop taking the medicine unless the doctor tells you to as it is important to control your fits.

Do not take the medicine if you:

- Are allergic to barbiturates.
- Are allergic to any ingredients listed in section 6.
- Suffer from severe lack of breath.
- Have a severe liver or kidney disorder.
- Have porphyria – where chemicals in the body do not break down normally.
- Are a child who is hyperactive.

Talk to your doctor or pharmacist if you have:

- Existing liver disease.
 - Kidney disease.
 - Severe shortage of breath.
 - Restricted movement.
 - Or are due to have a flu (influenza) vaccination.
- Your doctor may prescribe additional Vitamin D supplements especially if you have been immobile for a long time, if you don't get much sunlight or your diet is low in vitamin D or calcium. If you think any of these apply to you talk to your doctor.

Tell your doctor if you are taking any of the following:

- **Alcohol.**
- **Anticoagulants** - which are used to thin the blood (e.g. warfarin).
- **Antibiotics** (e.g. tetracyclines, cefotaxime, metronidazole, telithromycin, chloramphenicol).
- **Anti-inflammatory medicines** known as **corticosteroids** (e.g. prednisolone, betamethasone).
- **Antihistamine** medicines for **allergies** (e.g. chlorphenamine, promethazine).
- **Antismoking medicines** (e.g. amfebutamone, bupropion).
- **Anti viral** medicines for **HIV** (e.g. nelfinavir, indinavir, saquinavir, abacavir, amprenavir, darunavir, fosamprenavir, lopinavir, etravirine, ritonavir, tipranavir).
- Medicines to treat **arthritis or rheumatism** (e.g. methotrexate).
- Medicines used to help with **asthma or breathing** (e.g. theophylline, montelukast).
- Medicines to treat some **cancers, leukaemia or Hodgkin's disease** (e.g. doxorubicin, etoposide, ifosfamide, procarbazine, irinotecan, teniposide, cyclophosphamide, gefitinib).
- **Ciclosporin or tacrolimus**, used in organ and tissue transplants.
- Medicines used to treat **depression** (e.g. MAOIs, imipramine, amyltriptyline, paroxetine, SSRIs, fluoxetine, mianserin, lithium).
- Medicines to treat **diabetes** (e.g. chlorpropamide, tolbutamide).
- **Diuretic medicines** to reduce water in the body (e.g. furosemide, eplerenone, acetazolamide).
- Other medicines to treat **epilepsy** (e.g. phenytoin, carbamazepine, lamotrigine, sodium valproate, clonazepam, diazepam, tiagabine, zonisamide, ethosuximide, oxcarbazepine, felbamate, stiripentol, vigabatrin, primidone).
- **Folic acid** used to treat **anaemia**.
- Medicines used to treat **fungal infections** (e.g. griseofulvin, itraconazole, posaconazole, voriconazole).
- **Flu (influenza) vaccine**. Talk to your doctor before having a flu vaccination if taking phenobarbital.
- Medicines for **heart problems, high blood pressure and angina** (e.g. propranolol, timolol, metoprolol, felodipine, isradipine, dihydropyridines, diltiazem, verapamil, digitoxin, disopyramide, lidocaine, propafenone, dronedarone, quinidine).
- **Hormones** and related medicines (e.g. tibolone, gestrinone, toremifene).
- **Lofexidine** - used to treat opioid overdose.
- Medicines used to treat **malaria** (e.g. quinine).
- **Memantine** - for Alzheimer's disease.
- **Methadone**, a medicine used to treat drug dependency.
- **Methylphenidate** - for ADHD.
- Medicines which prevent **nausea and vomiting** (e.g. topisetron, aprepitant).
- Medicines for **psychiatric disorders** (e.g. chlorpromazine, haloperidol, mesoridazine, thioridazine, aripiprazole).
- **Painkillers, sedatives or anaesthetics** (e.g. morphine, dextropropoxyphene, pethidine, fenopropfen, paracetamol, diazepam, lidocaine).
- **Rifampicin**, a drug used to treat **tuberculosis**.
- **Sodium oxybate** - for serious daytime sleepiness.
- **Thyroxine**, a drug which treats an **under active thyroid**.
- Medicines to treat **Vitamin B6 deficiency** (e.g. pyridoxine).

Important

- The herbal remedy **St Johns Wort** (hypericum perforatum) should not be taken at the same time as this medicine. If you already take St John's Wort, talk to your doctor before stopping the St John's Wort preparation.
- **Steroid medicines including oral contraceptives or emergency contraceptives (morning after pill)** – Using Phenobarbital may cause your oral contraceptive to be less effective, and it may not prevent pregnancy. An alternative contraceptive medicine may be more appropriate when taking Phenobarbital. You should discuss this with your doctor before taking this medicine.

Pregnancy and breast feeding

If you are pregnant or planning to become pregnant you should speak to your doctor before taking Phenobarbital. If you become pregnant whilst taking Phenobarbital your doctor will decide if you should continue taking this medicine or whether another would be more suitable during your pregnancy.

Do not stop taking Phenobarbital until you have seen your doctor as it is important to control your fits. If taken during pregnancy (particularly during the first 3 months and the last 3 months) Phenobarbital may cause birth defects. It may also cause problems with bleeding in your baby when it is born. Use of Phenobarbital during pregnancy may lead to drug dependence and sleepiness in the newborn baby. However, your doctor may decide that it is very important that you continue to take Phenobarbital. He or she will explain the risks to you.

Turn over ↗

Adequate supplements of folic acid should be taken before conception and during pregnancy.

As Phenobarbital is released into breast milk this may make your baby sleepy or get too little oxygen and therefore breast feeding is not advisable.

Use by children

This product may be used by children. The doctor will take into account the weight and the age of the child and prescribe the correct dose.

Driving and using machinery

This product may cause drowsiness. The amount of alcohol may impair your ability to drive or use machines.

If affected do not drive or operate machinery. Consult your doctor for further information.

Important information about some of the ingredients of this medicine

This medicine contains 1.6g of alcohol (ethanol) in each 5ml (i.e. up to 21g based on a 65ml dose). The amount in 5ml of this medicine is equivalent to 39ml beer or 16ml wine (i.e. up to 501ml beer or 208ml wine based on a 65ml dose). The alcohol in this preparation is likely to affect children. These effects include feeling sleepy and change in behaviour. It may also affect their ability to concentrate and take part in physical activities. The amount of alcohol in this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react. If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine. The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine. If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

This medicine contains 0.0078mg benzyl alcohol in each 5ml dose (i.e. up to 0.1mg in each 65ml dose) which may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called gasping syndrome) in young children. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

The product also contains a large proportion of glycerol. This may cause headache, stomach upset and diarrhoea. It also contains tartrazine (E102) and sunset yellow FCF (E110) colours, which may cause allergic reactions.

3. How to take the medicine

This medicine has been prescribed for you personally. Do not pass it on to others as it may harm them. Always take your medicine as prescribed by your doctor.

Dose

Take this medicine by mouth.

Adults

The usual adult daily dose is between 20 and 65ml. The doctor will decide the exact amount that you should take each day.

Children

The doctor will prescribe the correct dose for the child depending on their age and weight.

As your treatment progresses, the doctor may want to vary the amount you take each day, or when you take it. The doctor may want you to take all the medicine at one go each day, or he may ask you to take the medicine in 2 or 3 portions throughout the day.

Always follow the dose instructions given by your doctor carefully.

If you miss a dose take the next as soon as you remember. **Do not** take a double dose. You can then carry on with the next dose at the correct time. Missing doses may risk withdrawal symptoms.

If you take too much see a doctor immediately.

Stopping this medicine

Stopping this medicine abruptly may cause severe withdrawal symptoms including a return of your seizures. If you want to stop taking the medicine for any reason you must talk about this with your doctor before stopping.

4. Possible side effects

Like all medicines Phenobarbital Elixir can have side effects although these don't affect everyone.

Important side effects to look out for – and what to do if you are affected.

If you think you have any of these side effects, see a doctor immediately.

- Thoughts of harming or killing yourself.
- Fever, skin rashes/eruptions or skin yellowing.
- Skin sores or mouth ulcers.

- Bruising or bleeding.
- Shedding or peeling of the skin.
- Swollen glands.

Other possible side effects

These side effects are usually mild and may disappear after a few days - if they are severe or last for longer than a few days, tell your doctor.

- Drowsiness.
- Lack of energy.
- Unsteady walking or jerky movements.
- Memory problems, difficulty in concentrating, confusion.
- Depression.

Other side effects which may occur are:

- Headache.
- Insomnia (sleeplessness).
- Difficulty breathing.
- Skin itching.
- Sensitivity to light.
- Seeing things.
- Jerky eye movements.
- Small mood changes.
- Changes in behaviour including hyperactivity, irritability and aggression.
- Dizziness.
- Restlessness, feeling excited or agitated.
- Children - may become irritable and hyperactive.
- Reduced levels of folate, Vitamin K, phosphate or calcium in the blood.
- Reduced thyroid hormones in the blood.
- Anaemia or low white blood cells.
- Problems with levels of Vitamin D in the body.
- Problems with inflammation of tendons (e.g. Dupuytren's contracture of the hand, frozen shoulder, Ledderhose's syndrome of the foot, Peyronie's disease of the penis).
- Fibromas (non-cancerous growths).
- Problems with bile and the liver (including inflammation).
- Softening of the bones, rickets and general joint pain.
- Low blood pressure.
- Fits (Grand Mal convulsion).
- Using this medicine for a long time may lead to dependence and withdrawal problems when you stop taking it (see section 3).
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term antiepileptic medication, have a history of osteoporosis, or take steroids.

If you have any of these side effects or notice any other effects not mentioned here, tell your doctor or pharmacist. They will advise you what to do.

Reporting of side effects

If you get 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing this medicine

Do not use the product after any expiry date which may appear on the label.

Keep out of the sight and reach of children.

Keep your medicine locked in a cupboard if possible.

Do not store the product above 25°C. Once opened use within 28 days.

Protect from light.

Medicines should not be disposed of via wastewater or household waste. Return any unused medicine to your pharmacist. These measures will help protect the environment.

6. Further information

What the medicine contains

The active substance is Phenobarbital 15mg per 5ml.

The other ingredients are anise oil, coriander oil, ethanol, glycerol (E422), orange oil terpeneless, lemon oil terpeneless, tartrazine (E102), sunset yellow dye (E110) and purified water.

What the medicine looks like

The medicine is a deep yellow liquid.

Marketing Authorisation Holder and Manufacturer

Thornton and Ross Ltd., Huddersfield, HD7 5QH, England.

This leaflet was last revised in

September 2020