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.

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 Thornton & Ross 15mg/5ml Elixir contains a significant amount of alcohol.

You may cause wakefulness, excitement and delirium, unless taken with a painkiller. If you have severe pain, Phenobarbital may not produce a calming action, and you have these thoughts, immediately contact your doctor.

If you have liver disease or if this medicine is prescribed for a restricted movement.

Kidney disease.

Existing liver disease.

Talk to your doctor or pharmacist if you have:

Are a child who is hyperactive.

Suffer from severe lack of breath.

Antismoking medicines

Antihistamine

Hormones

Diuretic medicines

Medicines to treat depression

Medicines used to treat metabolic disorders

Medicines for bone diseases

Medicines to treat tuberculosis

Sodium oxide - 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 John’s 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.

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

- Alcohol

- Antineoplastics - which are used to thin the blood (e.g. warfarin).

- Antibiotics (e.g. tetracyclines, cefoxaxime, metronidazole, telithromycin, chloramphenicol).

- Anti-inflammatory medicines known as corticosteroids (e.g. prednisolone, bremelanotide).

- Antibhistamines for allergies (e.g. chlorphenamine, promethazine).

- Antimicking medicines (e.g. amfebutamone, burproupon).

- Anti-viral medicines for HIV (e.g. nevirapine, indinavir, saquinavir, abacavir, amenosavine, daznarcin, fosamprovar, loxapin, 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, arinostat, temposide, cyclophosphamide, gefinhib).

- Ciclosporin or tacrolimus, used in organ and tissue transplants.

- Medicines used to treat depression (e.g. MAOIs, imipramine, amitryptiline paroxetine, SSRIs, fluoxetine, mianserin, lithium).

- Medicines to treat diabetes (e.g. chlorpropamide, tolbutamide).

- Diuretic medicines to reduce water in the body (e.g. furosemide, zepetone, azetadizamide).

- Other medicines to treat epilepsy (e.g. phenytoin, carbenazepine, lamotrigine, sodium valproate, cloxzamam, diazepam, tiagabine, zonisamide, ethosuximide, oxcarbazepine, felbamate, stripitol, vagabatrin, primidone).

- Folac acid used to treat anaemia.

- Medicines used to treat fungal infections (e.g. griseofulvin, itaconazole, 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, metolol, metoprolol, feldopidine, isradipine, atenolol-peridines, diltiazem, verapamil, digitoxin, disopyramide, lidocaine, propafenon, dronedarone, quindine).

- Hormones and related medicines (e.g. tibolone, gestrinone, toremifene).

- Lofexadine - used to treat opioid overdose.

- Medicines used to treat malaria (e.g. quinine).

- Memantine - for Alzheimer’s disease.

- Medications used in medicine used to treat drug dependency.

- Methylphenidate - for ADHD.

- Medicines which prevent nausea and vomiting (e.g. topisometon, aprepitant).

- Medicines for psychiatric disorders (e.g. chlorpromazine, haloperidol, mesoridazine, thioridazine, zipreparin).

- Painkillers, sedatives or anaesthetics (e.g. morphine, dextropropoxyphene, pethidine, fenotropin, paracetamol, dexameth, lidocaine).

- Rifampcin, a drug used to treat tuberculosis.

- Sodium oxide - for serious daytime sleepiness.

- Thyroxine, a drug which treats an under active thyroid.

- Medicines to treat Vitamin B6 deficiency (e.g. pyridoxine).

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.

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.

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

Now read the rest of the leaflet before you use this medicine. It includes other information which might be especially important for you.
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. Adequate supplements of folate 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 38vol% of ethanol (alcohol), i.e. up to 20g per daily dose, equivalent to 513ml beer or 214ml wine per day. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast feeding women, children and high risk groups, such as patients with liver disease or epilepsy. This amount of alcohol may alter the effects of other medicines taken at the same time. The amount of alcohol in this product may impair your ability to drive or use machines. You must avoid other alcoholic drinks when taking this medicine.

The product also contains a large proportion of glycerol. This may cause blocked or blocked up 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 and 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 rash/eczema or skin yellowing.
• Skin sores or mouth ulcers.
• Bruising or bleeding.
• Shaking or feeling 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.
• Fis (Grand Mal convolution).
• 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 FCF (E110) and purified water.

What the medicine looks like
The medicine is a deep yellow liquid.

Marketing Authorisation Holder and Manufacturer

This leaflet was last revised in January 2016.