

Package Leaflet: Information for the user

Phenobarbital 15 mg Tablets Phenobarbital 30 mg Tablets Phenobarbital 60 mg Tablets

Phenobarbital

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets 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 PHENOBARBITAL TABLETS ARE AND WHAT THEY ARE USED FOR

Phenobarbital tablets belong to a group of medicines called barbiturates. These medicines reduce brain activity which would otherwise cause fits or seizures in epilepsy, except absence seizures (day dreaming).

2. BEFORE YOU TAKE PHENOBARBITAL TABLETS

Do not take Phenobarbital tablets and **tell** your doctor if you have:

- An allergy (hypersensitivity) to phenobarbital, other barbiturates or to any of the other ingredients in this medicine (see section 6, "Further information")
- **Porphyria** (a genetic or inherited disorder of the red blood pigment haemoglobin)
- **Severe breathing difficulties**
- **Severe kidney or liver disease**
- **Addison's disease** (a condition affecting the adrenal glands)

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.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Phenobarbital, appearing initially as reddish target like spots or circular patches often with central blisters on the trunk.

Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest occurrence of serious skin reactions is within the first week of treatment. If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of Phenobarbital, you must not be restarted on Phenobarbital at any time.

If you develop a rash or these skin symptoms, seek immediate medical advice from a doctor and tell him that you are taking this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal remedies, health foods or supplements that you have obtained without a prescription. It is particularly important to tell the doctor if you are taking:

- Disopyramide and quinidine (to **treat irregular heartbeats**)
- Chloramphenicol, doxycycline, metronidazole, rifampicin, telithromycin, griseofulvin, itraconazole, voriconazole, lopinavir, indinavir, nelfinavir and saquinavir (to **treat infections**)
- Medicines used to thin the blood such as **warfarin**
- Mianserin, nortriptyline, tricyclic antidepressants or St John's wort (*Hypericum perforatum*) a herbal remedy (to **treat depression**)
- Phenytoin, sodium valproate, carbamazepine, lamotrigine and ethosuximide (to **treat epilepsy**)
- Chlorpromazine, thioridazine, haloperidol and clonazepam (to **treat mental illness**)
- Verapamil, nimodipine, and propranolol (to **treat high blood pressure**)
- Nifedipine (to treat **angina and high blood pressure**)
- Digoxin (to treat **certain heart conditions**)
- Ciclosporin (to **prevent organ transplant rejection**)
- **Steroids** such as prednisolone and dexamethasone
- Folic acid or vitamin D (**supplements**)
- **Cimetidine** (to **treat ulcers**)
- Toremifene (to **treat some cancers**)
- **Methadone** (used in severe pain or drug addiction)
- **Pethidine** (used to relieve severe pain)
- **Oral contraceptives** (talk to your doctor about the best method of contraception for you)
- **Thyroxine** (thyroid hormone)
- Montelukast or theophylline (to **treat asthma**)
- Tropisetron (to **treat nausea and vomiting**)
- **Memantine** (to treat dementia)

Do not drink alcohol without consulting with your doctor first as it increases the effects of phenobarbital.

Pregnancy and breast-feeding

Your doctor should discuss the possible effects of Phenobarbital tablets on the unborn child and the risks and benefits of treatment should be considered carefully. Check with your doctor before taking folic acid supplements as they interact with Phenobarbital tablets, your doctor may need to adjust your dose. If you are taking Phenobarbital tablets, do not breastfeed, as the medicine will pass into the breast milk and may harm the baby.

Driving and using machines

Phenobarbital tablets may make you feel less alert than normal. Make sure you are not affected before driving or operating machinery.

Important information about some of the ingredients of Phenobarbital tablets:

Phenobarbital tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Phenobarbital 60mg tablets contain 0.05 mg sunset yellow (E110) per tablet, which may cause allergic reactions.

3. HOW TO TAKE PHENOBARBITAL TABLETS

Always take Phenobarbital tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

You are advised **not to drink alcohol**, check with your doctor if you have any questions. Swallow the tablets **with water** at the same time each day.

Doses:

- **Adults:** 60mg-180mg daily usually taken at night.
- **Children:** 5mg-8mg per kg of bodyweight a day.
- **Elderly:** your doctor may prescribe a lower dose.

If you stop taking Phenobarbital tablets

If you stop taking the tablets you may develop withdrawal effects such as sleeplessness, anxiety, tremor, dizziness, feeling sick, fits and delirium.

If you forget to take Phenobarbital tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose when it is due.

If you take more Phenobarbital tablets than you should

If you accidentally take too many tablets, contact your doctor or go to your nearest hospital casualty department immediately. Signs of an overdose include drowsiness, speech problems, jerky movements, jerky eye movements, loss of inhibition, reduced reflex response, low body temperature, low blood pressure and breathing problems.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Phenobarbital tablets can cause side effects, although not everybody gets them.

Stop taking Phenobarbital tablets and see your doctor immediately if you experience any of the following symptoms:

- Severe sudden **allergic reaction** with the following symptoms:
 - Rash
 - Itching
 - Difficulties in breathing or swallowing
 - Swelling of the face, lips, tongue or throat
- Jaundice (yellowing of the skin or whites of the eyes)

Other possible side effects:

- **Skin:** rashes, exfoliative dermatitis (scaling and itching of the skin with loss of hair), erythema multiforme (circular, irregular red patches), Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2).

- **Blood:** if you notice increased bruising, nosebleeds, sore throats or infections, excessive tiredness, breathless on exertion you should tell your doctor who may want to perform a blood test.
- **Mental health:** restlessness and confusion in the elderly, unusual excitement, depression, memory impairment, hallucinations.
- **Nervous system:** hyperactivity, hyperexcitability and irritability in children and the elderly, jerky movements, jerky eye movements, unsteady walking, loss of co-ordination, drowsiness, lethargy.
- **Respiratory depression** (difficulty breathing).
- **Hepatitis** (inflammation of the liver) and **cholestasis** (damaged bile system), seen as yellowing of the skin and whites of the eyes.
- **Hypocalcaemia** (low levels of calcium in the blood).
- **Vertigo** (dizziness or a feeling of ‘spinning’).
- **Sedation** (which may become less marked with continued treatment).
- **Osteomalacia** (softening of the bones).
- **Dupuytren's contracture** (fixed flexion contracture of the hand where the fingers bend towards the palm and cannot be fully extended (straightened)).
- **Hypotension** (low blood pressure).
- 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 any of these side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PHENOBARBITAL TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C. Keep the container tightly closed and protect from light. Do not take Phenobarbital tablets after the expiry date, which is stated on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Phenobarbital tablets contain

The active substance is phenobarbital.

Each tablet contains 15mg, 30mg or 60mg of the active substance phenobarbital.

The other ingredients are:

The other ingredients are pregelatinised maize starch, lactose monohydrate, sodium laurilsulfate, magnesium stearate, stearic acid, sodium starch glycollate.

The 15mg tablet also contains the colour quinoline yellow (E104).

The 60mg tablet also contains the colour sunset yellow (E110).

What Phenobarbital 15mg, 30mg and 60mg tablets look like and contents of the pack

Phenobarbital 15mg tablets are round, pale yellow, flat bevelled edge tablets, scored with a breakline on one face. The tablet can be divided into equal halves.

Phenobarbital 30mg tablets are round, white, biconvex tablets.

Phenobarbital 60mg tablets are round, pale orange, biconvex tablets.

Phenobarbital is available in polypropylene tubes with low density polyethylene caps.

Pack sizes are:

21, 100, 250, 500 and 1000 tablets

Not all pack sizes may be marketed.

Marketing authorisation holder/ Manufacturer:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland.

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