

## Package Leaflet: Information for the user

### Phenobarbital 15mg Tablets Phenobarbital 30mg Tablets

#### Phenobarbital

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Phenobarbital tablets are and what they are used for
2. What you need to know before you take Phenobarbital tablets
3. How to take Phenobarbital tablets
4. Possible side effects
5. How to store Phenobarbital tablets
6. Contents of the pack and other information

#### 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. What you need to know before you take Phenobarbital tablets

**Do not take** Phenobarbital tablets and **tell** your doctor

- if you are allergic to phenobarbital or any of the other ingredients of this medicine (listed in section 6)
- if you have **porphyria** (a genetic or inherited disorder of the red blood pigment haemoglobin)
- if you have **severe breathing difficulties**
- if you have **severe kidney or liver** disease
- if you have **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.

### **Other medicines and Phenobarbital tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 ethosuxamide (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**

If taken during pregnancy, phenobarbital can cause serious birth defects and can affect the way in which the child develops as it grows. Birth defects which have been reported in studies include cleft lip (split in the top lip) and cleft palate (split in the roof of the mouth) and heart abnormalities. Other birth defects have also been reported, such as malformation of the penis (hypospadias), smaller than normal head size, facial, nail and finger abnormalities. If you take phenobarbital during pregnancy you have a higher risk than other women of having a child with birth defects that require medical treatment. In the general population, the baseline risk of major malformations is 2-3%. This risk is increased by about 3 times in women taking phenobarbital.

Babies born to mothers using phenobarbital during pregnancy may also be at increased risk of being smaller than expected.

Neurodevelopmental disorders (delays in development due to disorders in brain development) have been reported among children exposed to phenobarbital during pregnancy. Studies on the risk of neurodevelopmental disorders remain contradictory.

Phenobarbital should not be used during pregnancy unless nothing else works for you.

Talk to your doctor immediately if you are pregnant. 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. Do not stop taking phenobarbital until you have discussed this with your doctor, as stopping the medication abruptly may increase the risk of developing seizures, which may have harmful effects on you and the unborn child.

If you have taken phenobarbital during the last third of the pregnancy, appropriate monitoring should be conducted to detect potential disorders in the newborn, such as seizures, excessive crying, muscle weakness, sucking disorders.

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.

#### *Woman of child-bearing potential/Contraception*

If you are a woman of childbearing age you should use effective contraception during treatment with phenobarbital and for two months after treatment. Phenobarbital may affect how hormonal contraceptives, such as the contraceptive pill, work and make them less effective at preventing pregnancy. Talk to your doctor, who will discuss with you the most suitable type of contraception to use while you are taking phenobarbital.

If you are a woman of childbearing age and are planning a pregnancy, talk to your doctor before you stop contraception and before you become pregnant about switching to other suitable treatments in order to avoid exposing the unborn baby to phenobarbital.

#### **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.

#### **Phenobarbital tablets contain lactose**

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

### **3. How to take Phenobarbital tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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.

#### **The recommended dose is**

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

#### **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

#### **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 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine 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.

### **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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Phenobarbital tablets**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

**Do not store above 25°C. Keep the container tightly closed and protect from light.**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Phenobarbital tablets contain**

The active substance is phenobarbital.

Each tablet contains 15 mg or 30 mg of phenobarbital.

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

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

### **What Phenobarbital 15 mg and 30 mg tablets look like and contents of the pack**

Phenobarbital 15 mg tablets are round, pale yellow, flat bevelled edge tablets, scored with a breakline on one face.

Phenobarbital 30 mg tablets are round, white, 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 and Manufacturer:**

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

**This leaflet was last revised in June 2021.**