

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**Phenobarbital Bristol Labs 15mg Tablets**  
**Phenobarbital Bristol Labs 30mg Tablets**  
**Phenobarbital Bristol Labs 60mg Tablets**

**Read all of this leaflet carefully before you start taking 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. 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

**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**

The name of your medicine is Phenobarbital 15mg or 30mg or 60mg tablets. The active substance is Phenobarbital.

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 have an allergy (hypersensitivity) to phenobarbital, other barbiturates or any of the other ingredients (listed in section 6)
- If you suffer from 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.
- Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Phenobarbital tablets, 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 risk for occurrence of serious skin reactions is within the first weeks of treatment.
- If you have developed Stevens-Johnson syndrome or toxic epidermal necrolysis with the use of phenobarbital, you must not be re-started on Phenobarbital at any time.
- If you develop a rash or these skin symptoms, stop taking Phenobarbital tablets, seek urgent advice from a doctor and tell him that you are taking this medicine.

**Warnings and precautions**

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.

Talk to your doctor or pharmacist before taking phenobarbital tablets if you:

- or the person taking these tablets are **young, run down, senile** or **have a history of drug abuse** or **alcoholism**
- have **kidney** or **liver** problems
- have **breathing difficulties**
- have **severe** or **long term pain**.

**Other medicines and Phenobarbital tablets**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially:

- disopyramide and quinidine (to **treat irregular heartbeats**)
- chloramphenicol, doxycycline, metronidazole, rifampicin, telithromycin, griseofulvin, itraconazole, posaconazole, voriconazole, abacavir, amprenavir, lopinavir, indinavir, darunavir, nelfinavir and saquinavir (to **treat infections**)
- medicines used to thin the blood such as **warfarin**
- mianserin, paroxetine, MAOI or tricyclic antidepressants or St Johns's wort (*Hypericum perforatum*) a herbal remedy (to **treat depression**)
- oxcarbazepine, primidone, phenytoin, sodium valproate, carbamazepine, lamotrigine, tiagabine, zonisamide, ethosuxamide and vigabatrin (to **treat epilepsy**)
- chlorpromazine, thioridazine, haloperidol, aripiprazole and clonazepam (to **treat mental illness**)
- isradipine, felodipine, verapamil, diltiazem, nimodipine, nifedipine, metoprolol, timolol and propranolol (to **treat high blood pressure**)
- digitoxin or eplerenone (to **treat certain heart conditions**)
- ciclosporin or tacrolimus (to **prevent organ transplant rejection**)
- **steroids** such as hydrocortisone or prednisolone
- folic acid or vitamin D (**supplements**)

- toremifene, gestrinone, irinotecan or etoposide (to **treat some cancers**)
- **methadone** (used in severe pain or drug addiction)
- **oral contraceptives** (talk to your doctor about the best method of contraception for you) or tibolone (female hormone)
- **levothyroxine** (thyroid hormone)
- montelukast or theophylline (to **treat asthma**)
- tropisetron and aprepitant (to **treat nausea and vomiting**)
- **memantine** (to treat dementia)
- **methylphenidate** (to treat attention deficit disorder)
- **sodium oxybate** (to treat narcolepsy).

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.

**Pregnancy**

What you should know about the use of antiepileptic drugs in pregnancy.

If you are pregnant, or think you may be pregnant, you must tell your doctor straight away and discuss possible risks the epilepsy medicine you are taking might pose to your unborn baby.

If you are planning to become pregnant you should discuss your epilepsy treatment with your doctor as early as possible before you become pregnant.

You should not stop your treatment without discussing this with your doctor. Suddenly stopping may lead to breakthrough seizures which may harm you and your unborn baby. It is important that your epilepsy is well controlled.

Taking phenobarbital during pregnancy increases the chance that the baby may have a physical birth abnormality. If taken during pregnancy, phenobarbital can cause serious birth defects and can affect the way in which the child develops as it grows. Studies with women treated with phenobarbital for epilepsy have shown that around 6-7 babies in every 100 will have serious physical birth abnormalities.

This compares to 2-3 babies in every 100 born to women who don't have epilepsy. The most common types of serious physical birth abnormalities (major congenital malformations) reported for phenobarbital include heart defects and, less commonly, cleft lip and palate defects. Other birth defects have also been reported, such as malformation of the penis (hypospadias), smaller than normal head size, facial, nail and finger abnormalities.

Studies have found that the risk of physical birth abnormalities increases with increasing dose of phenobarbital. Therefore, your doctor will prescribe you the lowest effective dose.

Taking more than one epilepsy medicine at the same time may also increase the risk of physical birth

abnormalities. Where possible, your doctor will consider using one epilepsy medicine only to control your epilepsy.

Your doctor may advise you to take folic acid if you're planning to become pregnant and while you're pregnant. Your doctor may adjust your phenobarbital dose when you take folic acid. This is because folic acid supplements may affect your blood levels of phenobarbital.

Some studies observed that taking phenobarbital during pregnancy increases the chance that the baby may have problems affecting learning and thinking abilities.

Studies have also shown that babies born to mothers who have taken phenobarbital are born of smaller size than expected compared to children of mothers who did not take 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.

**Women 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.

**Breast-feeding**

If you are taking Phenobarbital Tablets, do not breast-feed, as the medicine will pass into the breast milk and may harm the baby.

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#### Phenobarbital with food and drink and alcohol

- You are advised not to drink alcohol whilst taking these tablets as it may interfere with the action of 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 contains Lactose

- If you have been previously told by your doctor that you have intolerance to some sugars (such as lactose), contact your doctor before taking this medicine.

#### Tests

- If you see another doctor or go into hospital or need a blood or urine test, let them know what medicines you are taking as Phenobarbital tablets may interfere with the results.

### 3. How to take Phenobarbital Tablets

- Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The tablets should be swallowed with a drink of water at the same time each day.

#### The usual dose is:

##### Adults and children over 12 years

- 60mg to 180mg daily taken at night.

##### Children under 12 years

- Your doctor will calculate the appropriate dose based on the child's body weight

#### Elderly

- Your doctor may prescribe a lower dose.

#### If you take more of Phenobarbital tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor 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 at the right time.

#### 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.

### 4. Possible Side Effects

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

#### If you get any of the following side effects, stop taking these tablets and tell your doctor immediately, or contact the casualty department at your nearest hospital:

- Allergic reaction:** skin rash, fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.
- Skin:** Rashes, erythema multiforme (circular, irregular red patches), lumps in the armpits or groin area. Potentially life-threatening skin rashes (Stevens Johnson syndrome - severe skin rash with flushing, fever, blisters or ulcers and toxic epidermal necrolysis - severe rash involving reddening, peeling and swelling of the skin that resembles severe burns) have been reported very rarely (see section 2).
- Liver:** inflammation of the liver (hepatitis), damaged bile system (cholestasis). Seen as yellowing of skin and whites of eyes.

#### Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Blood:** altered numbers and types of blood cells, if you notice increased bruising, nosebleeds, sore throats or infections, you should tell your doctor who may want to perform a blood test.
- Muscle, bone and connective tissue:** Problems with inflammation of tendons (e.g. Dupuytren's contracture of the hand, frozen shoulder), joint pain (arthralgia), bone softening and bone disease.

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.

- Reproductive system:** Scar tissue formation in the penis that can cause various penis problems (Peyronie's disease of the penis)
- Mental health:** restlessness and confusion in the elderly, unusual excitement, depression, memory impairment, hallucinations.
- Nervous system:** hyperactivity, behavioural disturbances in children, jerky movements, jerky eye movements, drowsiness, lethargy.
- Heart:** low blood pressure.
- Lungs:** difficulty breathing.
- Kidneys:** changes in the amount or need to pass water.

#### 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date (EXP.) which is stated on the carton. The expiry date refers to the last day of that month.
- 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.
- The other ingredients are pregelatinised maize starch, lactose, maize starch, stearic acid, purified water.

#### What Phenobarbital tablets look like and contents of the pack

- Phenobarbital 15mg, 30mg and 60mg tablets are smooth unmottled tablets showing no evidence of chipping or capping; free from specks and extraneous matter; odorless.
- Phenobarbital 15mg Tablets are available in pack of 28 tablets.
- Phenobarbital 30mg Tablets are available in pack of 28 tablets.
- Phenobarbital 60mg Tablets are available in pack of 28 tablets.

#### Marketing Authorisation Holder

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#### Phenobarbital Bristol Labs 15mg Tablets, PL 17907/0175

#### Phenobarbital Bristol Labs 30mg Tablets, PL 17907/0176

#### Phenobarbital Bristol Labs 60mg Tablets, PL 17907/0177

This leaflet was last revised in October 2021

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