PHENOBARBITAL 30MG TABLETS BP
PL 15755/0039

PHENOBARBITAL 60MG TABLETS BP
PL 15755/0040

UKPAR

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LAY SUMMARY

The MHRA granted OBG Pharmaceuticals Limited Marketing Authorisations (licences) for the medicinal products Phenobarbital 30mg Tablets BP (PL 15775/0039) and Phenobarbital 60mg Tablets BP (PL 15755/0040) on 9th January 2007. These are prescription-only medicines (POM) for the treatment of all forms of epilepsy except absence seizures.

Phenobarbital tablets contain the active ingredient phenobarbital, a barbiturate that neutralises the excessive electrical activity that builds up in the brain during an epileptic fit.

These applications are duplicates of previously granted applications for Phenobarbital Tablets BP 30mg and 60mg (PL 00790/0024-0025) which is currently licensed to Clonmel Healthcare Limited.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Phenobarbital 30mg Tablets BP and Phenobarbital 60mg Tablets BP outweigh the risks, hence Marketing Authorisations have been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted marketing authorisations for the medicinal products Phenobarbital 30mg Tablets BP (PL 15775/0039) and Phenobarbital 60mg Tablets BP (PL 15755/0040) to OBG Pharmaceuticals Limited on 9th January 2007. The products are prescription-only medicines.

The applications were submitted as simple abridged applications according to article 10.1(a)(i) of Directive 2001/83/EC, cross-referring to Phenobarbital Tablets BP 30mg and 60mg (PL 00790/0024-0025), which were approved on 10th January 1981.

No new data was submitted nor was it necessary for these simple applications, as the data is identical to that of the previously granted cross-reference product. As the cross-reference products were granted prior to the introduction of current legislation, no PARs were generated for them.

The products contain the active ingredient phenobarbital, which is a barbiturate. Phenobarbital tablets are indicated for the treatment of all forms of epilepsy except absence seizures.

These applications for Phenobarbital 30mg Tablets BP and Phenobarbital 60mg Tablets BP were submitted at the same time and were assessed concurrently. Consequently, all sections of this Scientific Discussion refer to both products.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 15755/0039-0040
PROPRIETARY NAME:	Phenobarbital 30mg Tablets BP Phenobarbital 60mg Tablets BP
ACTIVE(S):	Phenobarbital
COMPANY NAME:	OBG Pharmaceuticals Limited
E.C. ARTICLE:	Article 10.1(a)(i) of Directive 2001/83/EC
LEGAL STATUS:	POM

1. INTRODUCTION

These are simple, piggy back applications for Phenobarbital 30mg Tablets BP and Phenobarbital 60mg Tablets BP submitted under Article 10.1(a)(i) of Directive 2001/83/EC. The proposed MA holder is "OBG Pharmaceuticals Limited, Reeds Lane, Moreton, Wirral, Merseyside, CH46 1DW."

These applications cross refer to standard abridged applications for Phenobarbital Tablets BP 30mg and 60mg (PL 00790/0024-0025), which are currently registered in the UK. These applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed names of the products are Phenobarbital 30mg Tablets BP and Phenobarbital 60mg Tablets BP. The products have been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The products contain phenobarbital, equivalent to 30 and 60mg of phenobarbital, respectively. They are to be stored in polypropylene tube with a low-density polyethylene cap in pack sizes of 28 and 1000 tablets. The proposed shelf-life (3 years) and storage conditions (Keep container tightly closed, store in original packaging and do not store above 25 degrees) are consistent with the details registered cross-reference products.

2.3 Legal status

On approval, the products will be subject to a medical prescription.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is OBG Pharmaceuticals Limited, Reeds Lane, Moreton, Wirral, Merseyside, CH46 1DW.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference products and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch size is stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specification for each product is consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
With the exception of magnesium stearate, no materials of animal or human origin are included in the product. A certificate of suitability has been provided for magnesium stearate to show the minimising of any risk of transmission of TSE. A declaration has been provided for lactose monohydrate to show that the lactose is sourced from healthy animals in the same conditions as milk for human consumption.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS
The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET/CARTON
PIL
The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

Carton and blister
The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the applications are acceptable. Marketing Authorisations should be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT

As these are duplicate applications to Phenobarbital Tablets BP 30mg and 60mg (PL 00790/0024-0025), no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for these applications are consistent with that previously assessed for the cross-reference products and as such has been judged to be satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

EFFICACY
Phenobarbital is a well known drug and has been used as an anticonvulsant in epileptics for many years. These applications are identical to previously granted applications for Phenobarbital Tablets BP 30mg and 60mg (PL 00790/0024-0025), which were approved on 10th January 1981.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference products which have been licensed in the UK since 1981. Extensive clinical experience with phenobarbital is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

PHENOBARBITAL 30MG TABLETS BP
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STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 02/08/2000.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 28/09/2000.
3	Following assessment of the application the MHRA requested further information on 12/10/2000, 14/03/2001, 30/07/2002, 07/10/2003, 01/11/2006, 17/02/2006 and 07/08/2006
4	The applicant responded to the MHRA's requests, providing further information on 08/03/2001, 30/07/2003, 07/02/2005, 19/01/2006, 07/08/2006 and 14/11/2006
7	The application was determined on 09/01/2007

PHENOBARBITAL 30MG TABLETS BP
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PHENOBARBITAL 60MG TABLETS BP
PL 15755/0040

STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

PHENOBARBITAL 30MG TABLETS BP
PL 15755/0039

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Phenobarbital 30mg Tablets BP

2. Qualitative and Quantitative Composition
Each Tablet contains Phenobarbital 30mg

For a full list of excipients see section 6.1.

3. Pharmaceutical Form
Tablets.

White, circular, biconvex tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications
For all forms of epilepsy except absence seizures.

4.2. Posology and Method of Administration
Adults and the elderly: 60 – 180 mg daily at night.

Caution must be exercised in the treatment of elderly patients with careful monitoring of their condition.

Children: 5 – 8 mg per kg bodyweight daily.

Administration: Oral; the tablets should be swallowed with water.

4.3. Contra-indications
- Known hypersensitivity to barbiturates.
- Hypersensitivity to any of the ingredients in this medicine.
- Acute intermittent porphyria.
- Severe respiratory depression.
- Severe impairment of renal and hepatic function.

4.4. Special Warnings and Precautions for Use
Phenobarbital should be used with caution in the young, debilitated or senile patients and those with renal impairment, existing liver disease or respiratory depression (should be avoided if severe).

Prolonged use may result in the dependence of the alcohol-barbiturate type and particular care should be taken in treating patients with a history of drug abuse or alcoholism.

Avoid sudden withdrawal to prevent rebound seizures.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as the tablet contains lactose.

4.5. Interactions with other Medicaments and other forms of Interaction
Phenobarbital may induce liver microsomal enzymes and the rate of metabolism of certain drugs can be increased and serum concentrations of the following drugs may be reduced: coumarin anticoagulants, phenytoin, carbamazepine, lamotrigine, phenylbutazone, systemic steroids including oral contraceptives (which may lead to contraceptive failure), griseofulvin, rifampicin, phenothiazines, tricyclic antidepressants, chloramphenicol, ciclosporin, calcium channel antagonists (especially felodipine, verapamil, nimodipine and nifedipine – may require an increase in dosage),

theophylline**,** anti-virals (e.g. indinavir and saquinavir), anti-arrhythmics (e.g. disopyramide and quinidine), digitoxin and high doses of folic acid.

Increased sedative effects may occur with phenytoin and sodium valproate. Concomitant administration of phenobarbital and other anti-epileptics may increase the toxicity of phenobarbital without a corresponding increase in the anti-epileptic effect.

Concurrent administration with alcohol may lead to an additive CNS depressant effect.

Phenobarbital has been shown to reduce the response to thyroxine. Prescribers should be alert for changes in the thyroid status if barbiturates are added or withdrawn from patients being treated for hypothyroidism.

The effect of phenobarbital can be reduced by concomitant use of the herbal remedy St. John's wort (Hypericum perforatum).

4.6. Pregnancy and Lactation

The use of phenobarbital in pregnancy, especially the first and third trimesters should be avoided unless it is considered to be essential. Phenobarbital can cross the placental barrier and there is an increased risk of teratogenicity. Neonatal bleeding may occur and prophylactic treatment with vitamin K1 for the mother before delivery (as well as for the neonate) is recommended.

Patients taking phenobarbital should be adequately supplemented with folic acid before conception and during pregnancy.

Phenobarbital is excreted into breast milk and there is a small risk of neonatal sedation. Breast feeding is therefore not advisable.

4.7. Effects on Ability to Drive and Use Machines

Phenobarbital may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving or operating machinery. If patients are affected they should not drive or operate machinery.

4.8. Undesirable Effects

Memory and cognitive impairment, hyperactivity and behavioural disturbance. Drowsiness, lethargy, mental depression. Ataxia, nystagmus and respiratory depression. Megaloblastic anaemia (due to folate deficiency). Hepatitis, cholestasis and osteomalacia have been associated with barbiturate administration.

Hypersensitivity reactions occur in a small proportion of patients; skin reactions are reported in 1 to 3% of patients receiving phenobarbital, and are most commonly maculopapular, morbilliform or scarlatiniform rashes. Severe reactions such as exfoliative dermatitis, erythema multiforme and toxic epidermal necrolysis are extremely rare.

4.9. Overdose

Drowsiness, coma, respiratory depression, hypotension and hypothermia. The duration and depth of cerebral depression varies with the dose and tolerance of the patient. Supportive measures alone may be sufficient if symptoms are mild. If within four hours of ingestion, gastric aspiration or lavage may be of benefit in adults. The prime objective of treatment is to maintain vital functions while the majority of the drug is metabolised by hepatic enzymes.

Given normal renal function, forced alkaline diuresis (maintaining the urinary pH at approximately 8 by intravenous infusion) may enhance the excretion of the drug from the kidneys. Charcoal haemoperfusion is the treatment of choice for the majority of patients with very severe barbiturate poisoning who fail to improve, or who deteriorate despite good supportive care.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic group: Barbiturates and derivatives, ATC code: N03A A02

The barbiturates reversibly depress the activity of all excitable tissues. The CNS is extremely sensitive and when barbiturates are given in sedative or hypnotic doses there is little effect on skeletal, cardiac or smooth muscle. The ability of phenobarbital to exert maximum anticonvulsant action at doses below those required for hypnosis, determine its clinical use as an anti-epileptic. It limits the spread of seizure and elevates the seizure threshold. Although a precise relationship between the therapeutic results and concentration in blood plasma does not exist, plasma concentrations of 10 to 25μg/ml are usually recommended for the control of epilepsy; 150μg/ml is the minimum for prophylaxis against febrile convulsion.

5.2. Pharmacokinetic Properties

Oral absorption of phenobarbital is complete but somewhat slow, peak concentrations in plasma occur several hours after a single dose. It is 40 to 60% bound to plasma proteins and bound to a similar extent in tissues including the brain. By the oral route the rate determining step in absorption from the empty stomach is dissolution and dispersal of the drug in the gastrointestinal tract. Absorption takes place mainly in the intestine. The volume of distribution is approximately 0.5 litres per kilogram. The plasma half-life of phenobarbital is about 100 hours in adults, somewhat longer in neonates while it is shorter and more variable in children. The pKa of phenobarbital is 7.3 and up to 25% of a dose is eliminated by pH dependent renal excretion of the unchanged drug. The amount excreted increases with increased alkalinity of the urine. The remainder is inactivated by hepatic microsomal enzymes. Although the drug competes with other weak acids for binding to plasma albumin the only clinically important displacement is that of thyroxine. The absorption of dicumarol and griseofulvin are decreased by phenobarbital.

5.3. Preclinical Safety Data

No preclinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Maize starch
Lactose monohydrate
Sodium laurilsulfate
Sodium starch glycolate (Type A)
Magnesium stearate
Stearic acid

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

3 Years

6.4. Special Precautions for Storage

Do not store above 25^0C.
Keep the container tightly closed.
Store in the original container.

6.5. Nature and Contents of Container

Polypropylene tubes with low density polyethylene caps.

Pack sizes: 28, 1000 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. MARKETING AUTHORISATION HOLDER

OBG Pharmaceuticals Ltd.
Reeds Lane,
Moreton,
Wirral CH46 1QW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 15755/0039

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/01/2007

10 DATE OF REVISION OF THE TEXT

09/01/2007

PHENOBARBITAL 60MG TABLETS BP
PL 15755/0040

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Phenobarbital 60 mg Tablets BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains Phenobarbital 60 mg.

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM
Tablets

Pale orange, circular, biconvex tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications
For all forms of epilepsy except absence seizures.

4.2. Posology and method of administration
Adults and the elderly: 60 – 180 mg daily at night.

Caution must be exercised in the treatment of elderly patients with careful monitoring of their condition.

Children: 5 – 8 mg per kg bodyweight daily.

Administration: Oral; the tablets should be swallowed with water.

4.3. Contraindications
- Known hypersensitivity to barbiturates.
- Hypersensitivity to any of the ingredients in this medicine.
- Acute intermittent porphyria.
- Severe respiratory depression.
- Severe impairment of renal and hepatic function.

4.4. Special warnings and precautions for use
Phenobarbital should be used with caution in the young, debilitated or senile patients and those with renal impairment, existing liver disease or respiratory depression (should be avoided if severe).

Prolonged use may result in the dependence of the alcohol-barbiturate type and particular care should be taken in treating patients with a history of drug abuse or alcoholism.

Avoid sudden withdrawal to prevent rebound seizures.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine as the tablet contains lactose.

Sunset yellow (E110) included in the tablets may cause allergic-type reactions including asthma. Allergy is more common in patients allergic to aspirin.

4.5. Interactions with other medicinal products and other forms of interaction
Phenobarbital may induce liver microsomal enzymes and the rate of metabolism of certain drugs can be increased and serum concentrations of the following drugs may be reduced: coumarin anticoagulants, phenytoin, carbamazepine, lamotrigine, phenylbutazone, systemic steroids including

oral contraceptives (which may lead to contraceptive failure), griseofulvin, rifampicin, phenothiazines, tricyclic antidepressants, chloramphenicol, ciclosporin, calcium channel antagonists (especially felodipine, verapamil, nimodipine and nifedipine – may require an increase in dosage), theophylline**,** anti-virals (e.g. indinavir and saquinavir), anti-arrhythmics (e.g. disopyramide and quinidine), digitoxin and high doses of folic acid.

Increased sedative effects may occur with phenytoin and sodium valproate. Concomitant administration of phenobarbital and other anti-epileptics may increase the toxicity of phenobarbital without a corresponding increase in the anti-epileptic effect.

Concurrent administration with alcohol may lead to an additive CNS depressant effect.

Phenobarbital has been shown to reduce the response to thyroxine. Prescribers should be alert for changes in the thyroid status if barbiturates are added or withdrawn from patients being treated for hypothyroidism.

The effect of phenobarbital can be reduced by concomitant use of the herbal remedy St. John's wort (Hypericum perforatum).

4.6. Pregnancy and lactation

The use of phenobarbital in pregnancy, especially the first and third trimesters should be avoided unless it is considered to be essential. Phenobarbital can cross the placental barrier and there is an increased risk of teratogenicity. Neonatal bleeding may occur and prophylactic treatment with vitamin K1 for the mother before delivery (as well as for the neonate) is recommended.

Patients taking phenobarbital should be adequately supplemented with folic acid before conception and during pregnancy.

Phenobarbital is excreted into breast milk and there is a small risk of neonatal sedation. Breast feeding is therefore not advisable.

4.7. Effects on ability to drive and use machines

Phenobarbital may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving or operating machinery. If patients are affected they should not drive or operate machinery.

4.8. Undesirable effects

Memory and cognitive impairment, hyperactivity and behavioural disturbance. Drowsiness, lethargy, mental depression. Ataxia, nystagmus and respiratory depression. Megaloblastic anaemia (due to folate deficiency). Hepatitis, cholestasis and osteomalacia have been associated with barbiturate administration.

Hypersensitivity reactions occur in a small proportion of patients; skin reactions are reported in 1 to 3% of patients receiving phenobarbital, and are most commonly maculopapular, morbilliform or scarlatiniform rashes. Severe reactions such as exfoliative dermatitis, erythema multiforme and toxic epidermal necrolysis are extremely rare.

4.9. Overdose

Drowsiness, coma, respiratory depression, hypotension and hypothermia. The duration and depth of cerebral depression varies with the dose and tolerance of the patient. Supportive measures alone may be sufficient if symptoms are mild. If within four hours of ingestion, gastric aspiration or lavage may be of benefit in adults. The prime objective of treatment is to maintain vital functions while the majority of the drug is metabolised by hepatic enzymes.

Given normal renal function, forced alkaline diuresis (maintaining the urinary pH at approximately 8 by intravenous infusion) may enhance the excretion of the drug from the kidneys. Charcoal haemoperfusion is the treatment of choice for the majority of patients with very severe barbiturate poisoning who fail to improve, or who deteriorate despite good supportive care.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Barbiturates and derivatives, ATC code: N03A A02

The barbiturates reversibly depress the activity of all excitable tissues. The CNS is extremely sensitive and when barbiturates are given in sedative or hypnotic doses there is little effect on skeletal, cardiac or smooth muscle. The ability of phenobarbital to exert maximum anticonvulsant action at doses below those required for hypnosis, determine its clinical use as an anti-epileptic. It limits the spread of seizure and elevates the seizure threshold. Although a precise relationship between the therapeutic results and concentration in blood plasma does not exist, plasma concentrations of 10 to 25μg/ml are usually recommended for the control of epilepsy; 150μg/ml is the minimum for prophylaxis against febrile convulsion.

5.2. Pharmacokinetic properties

Oral absorption of phenobarbital is complete but somewhat slow, peak concentrations in plasma occur several hours after a single dose. It is 40 to 60% bound to plasma proteins and bound to a similar extent in tissues including the brain. By the oral route the rate determining step in absorption from the empty stomach is dissolution and dispersal of the drug in the gastrointestinal tract. Absorption takes place mainly in the intestine. The volume of distribution is approximately 0.5 litres per kilogram. The plasma half-life of phenobarbital is about 100 hours in adults, somewhat longer in neonates while it is shorter and more variable in children. The pKa of phenobarbital is 7.3 and up to 25% of a dose is eliminated by pH dependent renal excretion of the unchanged drug. The amount excreted increases with increased alkalinity of the urine. The remainder is inactivated by hepatic microsomal enzymes. Although the drug competes with other weak acids for binding to plasma albumin the only clinically important displacement is that of thyroxine. The absorption of dicumarol and griseofulvin are decreased by phenobarbital.

5.3. Preclinical safety data

No preclinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Maize starch
Lactose monohydrate
Sodium laurilsulfate
Sodium starch glycolate (Type A)
Magnesium stearate
Stearic acid
Sunset yellow (E110)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years

6.4. Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.
Store in the original container.

6.5. Nature and contents of container

Polypropylene tablet containers with low density polyethylene caps.

Pack sizes: 28, 1000 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

OBG Pharmaceuticals Ltd.
Reeds Lane,
Moreton,
Wirral CH46 1DW

8. MARKETING AUTHORISATION NUMBER(S)

PL 15755/0040

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PHENOBARBITAL 30MG TABLETS BP
PL 15755/0039

PHENOBARBITAL 60MG TABLETS BP
PL 15755/0040

PRODUCT INFORMATION LEAFLET

PHENOBARBITAL 30 mg & 60 mg TABLETS BP

PATIENT INFORMATION LEAFLET

This leaflet provides a summary of the information available on your medicine; please read it carefully before you start to take your medicine. If you have any questions or are not sure of anything ask your doctor or pharmacist.

What is in this medicine?

Phenobarbital 30 mg tablets: White, circular tablets. Each tablet contains 30 mg of phenobarbital, the active ingredient.
Phenobarbital 60 mg tablets: Pale orange, circular tablets. Each tablet contains 60 mg of phenobarbital, the active ingredient.
Phenobarbital Tablets BP were previously known as Phenobarbitone Tablets BP.

The tablets also contain the inactive ingredients maize starch, lactose monohydrate, sodium laurilsulfate, sodium starch glycolate (Type A), magnesium stearate and stearic acid. The 60 mg tablets contain the colour sunset yellow E110.

Pack size: 28, 1000.

What is phenobarbital?

Phenobarbital belongs to a group of drugs known as barbiturates. In an epileptic fit excessive electrical activity builds up in the brain. Phenobarbital works by neutralising this excessive electrical activity.

MA Holder:
OBG Pharmaceuticals Ltd
Reeds Lane
Moreton
Wirral CH46 1DW

Manufacturer:
Clonmel Healthcare Limited
Waterford Road
Co. Tipperary
Ireland

What is this medicine for?

Phenobarbital is used to treat epilepsy.

What do you need to know before taking this medicine?

If the answer to any of the following questions is YES, DO NOT take this medicine without consulting your doctor. The doctor should be told if the person taking the medicine is young, debilitated, senile or has a history of alcohol abuse.

- Have you previously suffered an allergic reaction to a medicine containing phenobarbital or other barbiturates?
- Are you allergic to any other ingredients in this medicine? (See 'What is in this medicine?' above.)
- Do you suffer from the rare condition called porphyria?
- Do you have long-term kidney or liver problems?
- Do you have difficulty breathing?

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 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 in 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. However, your doctor may decide that it is very important that you continue taking phenobarbital. Your doctor will explain the risks to you.

As with all women, 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 and therefore breast feeding is not advisable.

Elderly people should take this medicine with caution.

If you feel drowsy when you start to take this medicine, DO NOT drive or operate machinery until this effect has worn off.

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

The colour sunset yellow (E110) in the 60 mg tablets may cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

Are you taking any other medicines?

Before taking these tablets you should tell your doctor about any other medicines you are taking, including those not on prescription. In particular tell your doctor if you are taking:

- Anticoagulants, which are used to thin the blood (e.g. warfarin).
- Chloramphenicol, an antibiotic used to treat eye and ear infections.

- Griseofulvin, a drug used to treat fungal infections of the skin.
- Steroids including oral contraceptives.
- Ciclosporin which is used in organ and tissue transplants.
- Other medicines to treat epilepsy (e.g. phenytoin, lamotrigine, carbamaz-epine and sodium valproate).
- Phenylbutazone, which is used to treat a painful condition of the spine.
- Rifampicin, a drug used to treat tuberculosis.
- Phenothiazines which are used to treat psychiatric disorders.
- Medicines used to treat depression (e.g. amitriptyline and imipramine).
- Medicines used to treat heart trouble (e.g. nifedipine, felodipine, verapamil and nimodipine).
- Theophylline, which is used to help your breathing.
- Thyroxine which is used to treat a disorder of the thyroid gland.
- 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, consult your doctor before stopping the St John's wort preparation.
- Antiviral medicines used in the treatment of HIV (e.g. indinavir and saquinavir).
- Medicines used to treat heart problems (e.g. disopyramide, quinidine and digitoxin).
- High doses of folic acid.

You should avoid drinking alcohol while taking Phenobarbital tablets.

How much of this medicine should you take?

You should take your medicine as directed by your doctor. The pharmacist's label should tell you how much to take and how often. If it does not or you are not sure ask your doctor or pharmacist.

Adults: The usual dose is 60 to 180 mg daily, taken at night.

Children: If this medicine is prescribed for a child make sure that the tablets are taken as stated on the pharmacist's label. The usual dose is 5 to 8 mg per kg of bodyweight per day.

- Swallow the tablets with a drink of water.
- If you forget to take a dose, take it as soon as you remember, then go on as before.
- Do not stop taking the tablets suddenly. Always ask your doctor first.

What if you have taken too many tablets?

If you or anyone else has swallowed a lot of the tablets all together contact your nearest hospital casualty department or doctor immediately.

What unwanted effects can this medicine have?

This medicine, like most other medicines, may cause unwanted effects in some people. If you experience any of the following contact your doctor IMMEDIATELY.

- Rash or skin eruptions
- Allergic reactions such as skin rashes and more severe reactions such as lumpy skin rashes, skin inflammation or flaking of the skin.
- A yellowing of your skin or the whites of your eyes.

The following side effects are usually mild and may disappear with continued treatment. If they are severe or last longer than a few days you should tell your doctor.

- Drowsiness
- Memory disturbances, difficulty in concentrating
- Lack of energy
- Depression
- Unsteady walking

Other side effects which may occur are:

- Changes in behaviour
- Difficulty breathing
- Anaemia
- Visual disorders
- Osteomalacia - an abnormal softening of bone

If you experience any of the above or are concerned about anything or you notice anything unusual contact your doctor.

How should you store this medicine?

This medicine should not be used after the expiry stated on the pack.

Do not store above 25°C. Keep the container tightly closed. Store in the original container.
The tablets are sensitive to moisture and light.

Keep all medicines out of the reach and sight of children

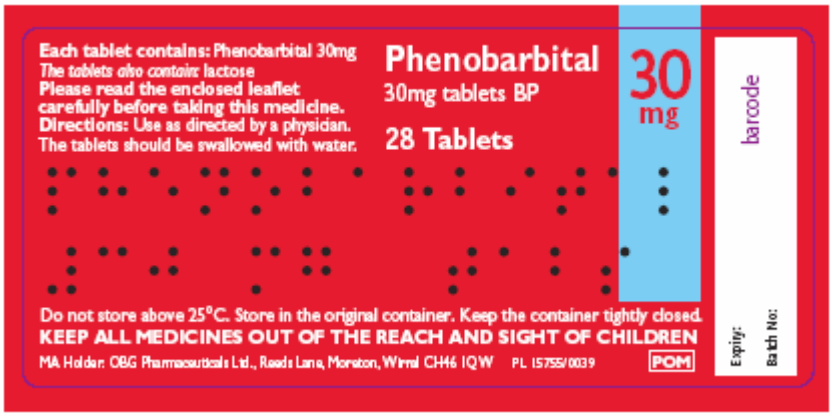
Remember: This medicine has been prescribed for you. Do not give it to anybody else even if their symptoms appear to be the same as yours, since it may be harmful to them.

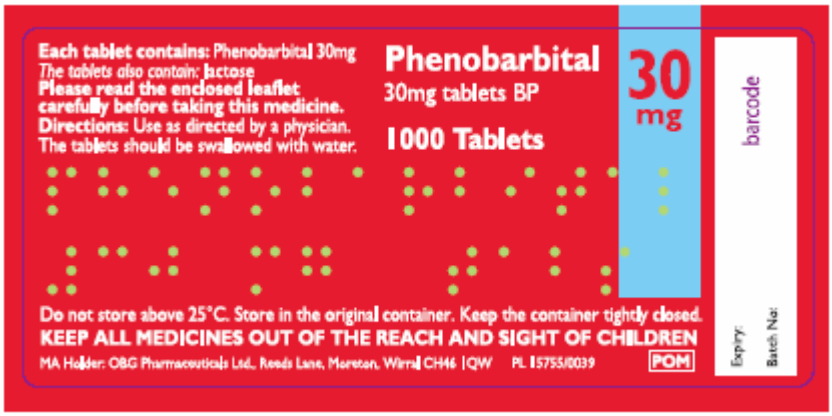
October 2005

PL 15755/0039
PL 15755/0040

PHENOBARBITAL 30MG TABLETS BP
PL 15755/0039

LABELLING





PHENOBARBITAL 60MG TABLETS BP
PL 15755/0040

LABELLING