

PHENOBARBITAL TEVA 15 mg, 30 mg AND 60 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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. See section 4.

What is in this leaflet:

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

1 What Phenobarbital is and what it is used for

The name of your medicine is Phenobarbital Teva 15 mg, 30 mg or 60 mg Tablets. Phenobarbital is a barbiturate (sedative), anticonvulsant drug which is used in the management of epilepsy to reduce the number and severity of fits.

Phenobarbital is used:

- to treat all forms of epilepsy except absence seizures (also known as petit mal in children).

2 What you need to know before you take Phenobarbital

Do NOT take Phenobarbital if you:

- are allergic to Phenobarbital or any of the other ingredients of this medicine (listed in section 6)
- are allergic to, or have ever had a specific individual reaction on taking barbiturates (sedatives)
- have problems with your kidneys or your liver
- have any problems with your breathing
- suffer from porphyria (a deficiency of specific enzymes within the body, causing an increase of substances called porphyrins).

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.

- **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 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, seek immediate advice from a doctor and tell him that you are taking this medicine.**

Tell your doctor before you start to take this medicine if you:

- see another doctor or go into hospital, let him or the staff know what medicines you are taking
- have a history of drug abuse or alcoholism
- have problems with your lungs, liver or kidneys
- are young, elderly or senile
- have severe or long term pain
- are pregnant, planning to become pregnant or breast-feeding.

Pregnancy, contraception in women, breast-feeding
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. Physical birth abnormalities 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.

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.

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. 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.

Pregnancy

Woman of child-bearing potential/Contraception

If you are a woman who is able to have a baby 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.

Other medicines and Phenobarbital

Do NOT take Phenobarbital in combination with

- the herbal remedy St John's Wort (*Hypericum perforatum*). If you already take St John's Wort, talk to your doctor before stopping the St John's Wort preparation.

Talk to your doctor if you are taking any of the following:

- anticoagulants, such as warfarin (used to stop the blood clotting)
- digitoxin, eplerenone (used to treat some heart conditions), disopyramide or quinidine (used to treat an abnormal heartbeat)
- drugs used to treat heart problems such as metoprolol, timolol and propranolol; calcium channel blockers, such as felodipine, isradipine, nicardipine, diltiazem, verapamil, nimodipine or nifedipine
- medicines used to treat infections, such as chloramphenicol, telithromycin, itraconazole, posaconazole, voriconazole, griseofulvin, doxycycline, metronidazole, rifampicin, indinavir, lopinavir, nelfinavir or saquinavir
- corticosteroids, such as hydrocortisone, cortisone or prednisolone
- ciclosporin (an immunosuppressant used following an organ transplant)
- tropisetron and aprepitant (used to stop you feeling and being sick following chemotherapy), irinotecan (used to treat cancer), toremifene (used to treat breast cancer)
- tibolone (used to treat osteoporosis), or gestrinone (used to treat endometriosis)
- liothyronine or levothyroxine (used to treat an under-active thyroid gland)
- phenytoin, sodium valproate, clonazepam, carbamazepine, vigabatrin tiagabine, ethosuximide, oxcarbazepine or lamotrigine (used to treat epilepsy)
- theophylline (used to treat asthma, bronchitis and emphysema), montelukast (used to prevent asthma)
- the non-steroidal anti-inflammatory drug phenylbutazone (used to treat spondylitis)
- oral contraceptives (the Pill)
- drugs to treat depression, such as mianserin, paroxetine, amitriptyline, moclobemide or dosulepin
- any drugs to treat a mental health problem, such as chlorpromazine, aripiprazole, thioridazine or haloperidol
- methadone (used as a painkiller); memantine (to treat dementia)
- methylphenidate to treat attention deficit disorder
- vitamin D or folic acid, your doctor may advise you to change your daily dose.

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

Phenobarbital with alcohol

Do not take alcohol whilst taking these tablets as it may interfere with the action of Phenobarbital.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor for advice before taking this medicine.

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.

- Check with your doctor before taking folic acid supplements as they interact with Phenobarbital tablets, your doctor may need to adjust your dose.

This medicine may harm your baby. Ask your doctor for advice if you intend to and before you breast-feed.

Driving and using machines

Phenobarbital may impair the mental and/or physical abilities required to drive or operate machinery. If affected do not drive or operate machinery.

Important information about some of the ingredients of Phenobarbital

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

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

The tablets should be swallowed preferably with a glass of water.

The recommended dose is:

Adults: 60-180 mg to be taken at night.

Children

The doctor will calculate the appropriate dose of Phenobarbital for your child based on the child's body weight.

Elderly

Your doctor will monitor you and may reduce your dose if necessary.

If you take more Phenobarbital than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause drowsiness, jerky eye movements, speech problems, lack of muscle control during movement or when swallowing, heart problems and/or attack, breathing problems, low blood pressure, low body temperature and coma.

Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Phenobarbital

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Phenobarbital

Do not stop taking Phenobarbital suddenly. If you suddenly stop taking this medicine, you may experience side effects such as dizziness, sleep disturbances or anxiety, headaches, feeling sick, fits, delirium and shaking. If you experience any of these side effects or any other side effects whilst stopping taking Phenobarbital, please speak to your doctor. If your doctor decides to stop your tablets, the dose will be gradually reduced.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

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

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- a syndrome called antiepileptic hypersensitivity syndrome. Symptoms of this include fever, rash, yellowing of the eyes and skin (hepatitis), and swollen glands.

These are very serious but rare side effects. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

- drowsiness, lethargy and depression
- problems with memory and general perception in the elderly
- lack of co-ordination and clumsiness
- involuntary movements of your eyes
- problems with your breathing, low blood pressure
- anaemia, a reduction in red blood cells

- characterised by headaches, weight loss and a sore mouth and tongue
- restlessness, confusion and excitability
- hyperactivity and behavioural problems in children
- hepatitis (inflammation of the liver)
- jaundice (a yellowing of the skin and whites of the eyes)
- softening and weakening of the bones
- a severe skin reaction may occur, which may cause scaly, itchy skin, or red, itchy spots, loss of hair and nails
- 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.
- bending contracture of the fingers into the palm of the hand
- stiffness and pain in the shoulder joint
- pain in the joints
- pain and curvature during erection
- potential life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported (see section 2) very rarely.

If used for extended periods Phenobarbital can become addictive. If you have any concerns about this, you should discuss them with your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 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

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

These tablets should be stored in the package or container supplied, do not transfer them to another container. Do not use Phenobarbital after the expiry date that is stated on the outer packaging. 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 Teva Tablets contain:

- The active ingredient is phenobarbital.
- The other ingredients are lactose monohydrate, maize starch, sodium starch glycolate (Type A), magnesium stearate (E572), dextrin.

What Phenobarbital Teva Tablets look like and contents of the pack:

- Phenobarbital 15 mg are white biconvex tablets marked "APS" over "0310" on one side and plain on reverse.
- Phenobarbital 30 mg are white biconvex tablets marked "APS" over "0311" on one side and plain on reverse.
- Phenobarbital 60 mg are white biconvex tablets marked "APS" over "0312" on one side and plain on reverse.
- Phenobarbital is available in pack sizes of 7, 10, 14, 21, 28, 30, 56, 60, 84, 90, 100, 110, 112, 120, 150, 160, 168 and 1000 tablets. In addition, the 15 mg and 30 mg tablets are available in pack sizes of 5000 tablets, and the 60 mg tablets in pack sizes of 500 tablets. See outer packaging or the pharmacy label for contents i.e. the number of tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

TEVA Pharmaceutical Works Private Limited Company, Pallagi street 13, Debrecen, H-4042, Hungary.

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