

Phenobarbital Accord 30mg and 60mg tablets

Read all of this leaflet carefully before you start taking 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.

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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

- 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 (see section 6)
 - **porphyria** (a genetic or inherited disorder of the red blood pigment haemoglobin)
 - **severe breathing difficulties**
 - **severe kidney or liver disease.**

If you develop a rash or the following skin symptoms, seek immediate advice from a doctor and tell that you are taking this medicine:

- 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 tablets you must not be re-started on Phenobarbital tablets at any time.

Check with 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.**

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.

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. 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 John'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**)
- 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

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.

Sugar intolerance

If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a type of sugar called lactose.

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

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 at night.
- **Children:** 5mg-8mg per kg of bodyweight a day.
- **Elderly:** your doctor may prescribe a lower dose.

If you take more 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 the 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 the 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.

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

- **Allergic reaction:** skin rash, fever, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.
- **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.
- **Liver:** inflammation of the liver (hepatitis), damaged bile system (cholestasis). Seen as yellowing of skin and whites of eyes.
- **Kidneys:** changes in the amount or need to pass water.
- **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).

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 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

Keep out of the sight and reach of children.
Stored below 25°C in a dry place.

Do not use Phenobarbital tablets after the expiry date stated on the label/carton/bottle. 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 (the ingredient that makes the tablet work) is phenobarbital. Each tablet contains either 30mg or 60mg of the active substance.
- The other ingredients are lactose, magnesium stearate, maize starch.

What Phenobarbital tablets look like and contents of the pack

Phenobarbital tablets are white, uncoated tablets.

Pack sizes are 28

Marketing Authorisation Holder and Manufacturer
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If you would like a leaflet with larger text, please contact 01271 385257.