- **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 Phenobarbital Tablets
Keep this medicine out of the sight and reach of children.
Store below 25°C. Keep the blister in the outer carton in order to protect from light.
Do not take this medicine after the expiry date 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 (the ingredient that makes the tablet work) is phenobarbital. Each tablet contains 15mg of the active substance.
- The other ingredients are lactose, starch, talc and stearic acid.

What Phenobarbital Tablets look like and contents of the pack
Phenobarbital 15mg Tablets are white circular tablets with flat bevelled edge, impressed "PN" on one face and "C" on the reverse. Nominal diameter 5.0mm.

Pack size is 28.

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Manufacturer
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If you would like a leaflet with larger text, please contact 01271 385257

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accord

Package leaflet: Information for the patient

Phenobarbital Accord 15mg 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 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 if you:
- are **allergic** to phenobarbital, other barbiturates or any of the other ingredients of this medicine (listed in section 6)
- have **porphyria** (a genetic or inherited disorder of the red blood pigment haemoglobin)
- have **severe breathing difficulties**
- have **severe kidney** or **liver** disease.

If you develop a rash or the following skin symptoms, seek immediate advice from a doctor and tell them 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 or 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.

Warnings and precautions
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**

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- 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.

Other medicines and Phenobarbital Tablets

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

- disopyramide and quinidine (to **treat irregular heartbeats**)
- chloramphenicol, doxycycline, metronidazole, rifampicin, telithromycin, griseofluvin, 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).

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Pregnancy, contraception in women, breast-feeding

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. 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.

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.

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

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conducted to detect potential disorders in the newborn, such as seizures, excessive crying, muscle weakness, sucking disorders

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.

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.

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.

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.

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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.
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 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.

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.

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.

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