

IDAMAN PHARMA PHENOBARBITONE TABLET

Phenobarbitone (30 mg)

What is in this leaflet

1. What Phenobarbitone Tablet is used for
2. How Phenobarbitone Tablet works
3. Before you use Phenobarbitone Tablet
4. How to use Phenobarbitone Tablet
5. While you are using Phenobarbitone Tablet
6. Side effects
7. Storage and disposal of Phenobarbitone Tablet
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Phenobarbitone Tablet is used for

Phenobarbitone Tablet is used for:

- short-term treatment of insomnia (difficulty falling or staying asleep)
- as a sedation to relieve anxiety, tension and apprehension
- treatments of seizures
- treatment of hyperbilirubinaemia (abnormally high level of bilirubin in the blood) in neonates or chronic intrahepatic cholestasis (decrease the flow of bile from the liver).

How Phenobarbitone Tablet works

Phenobarbitone Tablet belongs to a group of medicines called long-acting barbiturates. This medicine reduces brain activities. It is widely used in the treatment of seizures (epilepsy). It also has sedative effect and some protective action against all varieties of human partial and generalized epilepsy.

Before you use Phenobarbitone Tablet

-When you must not use it

Do not take Phenobarbitone Tablet and tell your doctor if you have:

- an allergy (hypersensitivity) to phenobarbitone, other barbiturates or any of the other ingredients
- porphyria (a genetic or inherited disorder of the red blood pigment haemoglobin)
- severe breathing difficulties
- severe kidney or liver disease

-Before you start to use it

Tell your doctor or pharmacist before taking this medicine if you:

- have rare hereditary problems of galactose intolerance, lactose intolerance (Lapp lactase intolerance) or galactose malabsorption
- have breathing difficulties
- have kidney or liver problems
- have acute chronic pain
- or the person taking these tablets are young, run down, senile or have a history of drug abuse or alcoholism

A small number of people being treated with antiepileptics such as phenobarbitone have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Ask your doctor about signs and symptoms of life-threatening skin reactions that have been reported with the use of phenobarbitone, including Stevens-Johnson Syndrome (SJS, a skin reaction with rash and blisters), Toxic Epidermal Necrolysis (TEN, skin rash often with blisters, lesions and lifting skin) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS, a skin reaction with itchy rash and fever). Closely monitor for skin reactions. Most often SJS, TEN and DRESS happen in the first few weeks of treatment. If symptoms or signs of

SJS, TEN or DRESS are present, phenobarbitone treatment should be stopped, and you should seek urgent medical treatment. The best results in managing SJS, TEN and DRESS come from early detection and stopping the drug treatment right away.

Pregnancy and lactation

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 phenobarbitone during pregnancy increases the chance that the baby may have a physical birth abnormality. The risk of physical birth abnormalities increases with increasing dose of phenobarbitone. 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 are planning to become pregnant and while you are pregnant. Folic acid supplementation

IDAMAN PHARMA PHENOBARBITONE TABLET

Phenobarbitone (30 mg)

during pregnancy can help to reduce the risk of neural defects to the infant.

If you are taking Phenobarbitone Tablet, do not breastfeed, as the medicine will pass into the breast milk and may harm the baby.

-Taking other medicines

Tell your doctor 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).

How to use Phenobarbitone Tablet

-How much to use

Usual Dose: 30 to 125mg, 3 times daily.

Up to 350mg daily can be given, in divided doses.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking Phenobarbitone Tablet for as long as your doctor recommends.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose. If you are unsure about whether to take your next dose, consult your doctor or pharmacist.

-If you use too much (overdose)

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, breathing problems, coma, cardiovascular collapse, cardiac arrest, decreased muscle tone and muscle dissolution.

While you are using Phenobarbitone Tablet

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Phenobarbitone Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor. Your doctor may want you to gradually reduce the amount of Phenobarbitone Tablet you are taking before stopping completely.

If you stop taking the tablets you may develop withdrawal effects such as sleeplessness, anxiety, tremor, dizziness, feeling sick, fits and delirium.

Do not take any new medicines without consulting your doctor.

Do not give Phenobarbitone Tablet to anyone else, even if they have the same symptoms or condition as you.

Follow all directions given to you by

IDAMAN PHARMA PHENOBARBITONE TABLET

Phenobarbitone (30 mg)

your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the ask your doctor or pharmacist for help.

-Things to be careful of

Driving and using machines: Phenobarbitone Tablet may make you feel less alert than normal. Make sure you are not affected before driving or operating machinery.

Alcoholic beverages:

If you drink alcohol, it could make some of the unwanted side effects of this medicine worse. Your doctor may suggest that you avoid alcohol completely or reduce the amount of alcohol you drink while you are taking.

Elderly:

Elderly patients may be more sensitive to the effect of barbiturates. They may react to usual doses of barbiturates with excitement, confusion or depression.

Children:

Some children may react to barbiturates with paradoxical excitement (effect of medical treatment which is opposite to the effect which would normally be expected).

Women of childbearing potential:

Using Phenobarbitone Tablet may cause your oral contraceptive to be less effective, and it may not prevent pregnancy. You may need a higher dose of oral contraceptives than usual to prevent pregnancy, or you may need to consider other forms of contraception. You should discuss this with your doctor if you want to take oral contraceptives while taking Phenobarbitone Tablet.

Phenobarbitone Tablet contains lactose:

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

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine:

- **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, drowsiness, lethargy, feeling faint, headache, nightmare or trouble sleeping and unusual irritability.
- **Nervous system:** Hyperactivity, behavioural disturbances in children, jerky movements, jerky eye movements.

- **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) and lumps in the armpits or groin area.
- **Hypersensitivity:** A rare, serious disorder in which your skin reacts severely to a medication (Stevens-Johnson syndrome [SJS] or Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS]). If symptoms or signs of SJS or DRESS (e.g. skin rash often with blisters or lesions) are present, phenobarbitone treatment should be stopped right away. Severe skin reaction where the upper surface of your skin detaches like a patient who has suffered burns (Toxic Epidermal Necrolysis [TEN]). If symptoms or signs of TEN (e.g. skin rash often with blisters or lesions and lifting skin) are present, phenobarbitone treatment should be stopped right away.

Side effects other than those listed here may also occur. Talk to your doctor about any side effect that seems unusual.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer ➔ Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of Phenobarbitone Tablet

-Storage

Keep all medicines out of sight and reach of children.

IDAMAN PHARMA PHENOBARBITONE TABLET

Phenobarbitone (30 mg)

Do not take this medicine after the expiry date stamped on the pack.

Keep in a dry place, below 30°C;
Protect from light.

-Disposal

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.

Product Description

-What it looks like

Round, clean, dry, uniform, even-edged, biconvex tablet and white in colour.

-Ingredients

-Active ingredient:

Each tablet contains Phenobarbitone 30mg.

-Inactive ingredient:

Lactose, Magnesium Stearate, Maize Starch, Sodium Benzoate, Sodium Starch Glycolate and Purified Water.

-MAL number

MAL19860219AZ

Product Registration Holder & Manufacturer:

Idaman Pharma Manufacturing Sdn Bhd (200401023395),
Lot 24 & 25, Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah Darul Aman, Malaysia

Date of Revision:

2/5/2023.

Serial Number:

BPFK(R4/1)071015/00345
