

PHENOBARBITONE TABLET

Phenobarbitone (30 mg)

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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.
- 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 barbiturates. It alters brain function and produces drowsiness, sedation and hypnosis. It also works by stabilising brain activity to prevent seizures. It lowers serum bilirubin concentration.

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 (see section **Product description**).
- 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 kidney or liver problems
- have breathing difficulties

Pregnancy and lactation

Phenobarbitone Tablet may affect your developing baby if you take it during pregnancy. Phenobarbitone is excreted in the breast milk. Use of Phenobarbitone Tablet by nursing mother may cause central nervous system depression in the infant.

Tell your doctor if you are pregnant, breastfeeding, or if you intend to become pregnant. Do not take Phenobarbitone Tablet until you and your doctor have discussed the risks and benefits involved.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking medicines below:

- Acetaminophen or paracetamol (to relief fever and pain)
- Steroids
- Antihypertensives (to reduce blood pressure)
- Antipsychotics (to treat mental disorder)
- Antidepressants (to treat mood disorder), e.g. tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs)
- Anticonvulsants (to treat fits), e.g. carbamazepine, valproic acid
- Central nervous system depressants and stimulants
- Anticoagulant (to treat blood clots), e.g. warfarin
- Digoxin (to treat heart disease)
- Antibiotics (to treat infections), e.g. doxycycline
- Steroids
- Oral contraceptives or emergency contraceptives (morning after pill) (see also Things to be careful of)

Other medicines not listed above may also interact with Phenobarbitone tablet. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use Phenobarbitone Tablet

- How much to use

Usual adult dose

30 to 125 mg, taken 3 times daily.

Doses up to 350 mg can be taken daily, 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)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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.

PHENOBARBITONE TABLET

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- *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.

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 your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, 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:

- **Allergic reaction:** skin rash, hives, fever, swelling of the face, lips, tongue, eyelids, or throat, or difficulty breathing, wheezing, tightness in chest, or swallowing.
- **Mental health:** restlessness and confusion in the elderly, unusual excitement, unusual tiredness or weakness, depression, memory impairment, hallucinations (hearing voices or seeing things which are not there).
- **Nervous system:** hyperactivity, behavioural disturbances in children, jerky eye movements, drowsiness, lethargy.
- Yellowing of eyes and skin
- Drowsiness
- Hangover effect
- Constipation
- Feeling faint, headache, nausea, vomiting
- Nightmare or trouble in sleeping
- Unusual irritability

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my

(Consumers → Reporting)

Storage and Disposal of Phenobarbitone Tablet

- *Storage*

Keep all medicines out of the sight and reach of children. Do not take this medicine after the expiry date stamped on the pack. Keep container tightly closed. Store below 25°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 and Sodium Starch Glycolate.

- *MAL Number:*

MAL19860219AZ

Manufacturer:

Idaman Pharma Manufacturing Sdn. Bhd (661901-P),
Lot 24 & 25, Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah Darul Aman.

Product Registration Holder:

Idaman Pharma Manufacturing Sdn. Bhd (661901-P),
Lot 24 & 25, Jalan Perusahaan Lapan, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah Darul Aman.

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