A Taj Pharmaceuticals Limited Brand

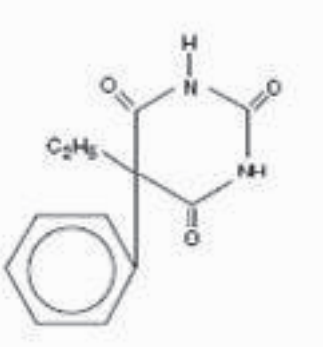
CROPRAM™
Phenobarbital Tablets, USP
15,30,60 and 100 MG

LICENCE NO: IND 88906/2004-09
PROPRIETARY NAME: Phenobarbital USP
Phenobarbital 15,30,60,100 mg Tablets USP
ACTIVE(S): Phenobarbital
COMPANY NAME: Taj Pharmaceuticals Limited
LEGAL STATUS: SCHEDULE- \V

A QUALITY DRUG FROM
Taj Pharmaceuticals Ltd. INDIA
A TAJ GROUP COMPANY
MUMBAI., INDIA

Generic Name: Phenobarbital (fee-noe-BAR-bih-tal)
Brand Name: CROPRAM™ Phenobarbital Tablets, USP 15,30,60 and 100 MG

Phenobarbital is used for:
Treating and preventing seizures, and treating sleep disorders. It may also be used for other conditions as determined by your doctor. **Phenobarbital is a barbiturate.** It works by depressing the central nervous system or brain. *In low doses, it causes mild sedation.* As the dose increases, it can cause sleep and even coma. As it causes the brain to relax, it also decreases seizure activity.



Do NOT use Phenobarbital if:

you are allergic to any ingredient in Phenobarbital
you have a history of the blood disorder porphyria
you are taking methoxyflurane, sodium oxybate (GHB), or voriconazole
you consume alcohol
you have liver problems or lung disease with breathing problems

Contact your doctor or health care provider right away if any of these apply to you.
Before using Phenobarbital:

Some medical conditions may interact with Phenobarbital. Tell your doctor or pharmacist if you have any medical conditions, especially if any of the following apply to you:

if you are pregnant, planning to become pregnant, or are breast-feeding
if you are taking any prescription or nonprescription medicine, herbal preparation, or dietary supplement
if you have allergies to medicines, foods, or other substances
if you have depression, pain, breathing problems, suicidal tendencies, or are in shock
if you have a history of substance abuse or dependence

Some **MEDICINES MAY INTERACT** with Phenobarbital. Tell your health care provider if you are taking any other medicines, especially any of the following:

Ethanol , MAO inhibitors (eg, phenelzine), quinine, sodium oxybate (GHB), stiripentol, or valproic acid because side effects such as increased sedation and difficulty breathing may occur
Ethanol, methoxyflurane, orsodium oxybate because the risk of their side effects may be increased by Phenobarbital
Anticoagulants (eg, warfarin), beta-blockers (eg, propranolol), clozapine, corticosteroids (eg, hydrocortisone), cyclosporine, doxorubicin, doxycycline, estrogens (eg, estradiol), imatinib, metronidazole, steroidal contraceptives (eg, birth control pills), theophylline, or voriconazole because their effectiveness may be decreased by Phenobarbital.

This may not be a complete list of all interactions that may occur. Ask your health care provider if Phenobarbital may interact with other medicines that you take. **Check with your health care provider before you start, stop, or change the dose of any medicine.**

How to use Phenobarbital:

Use Phenobarbital as directed by your doctor. Check the label on the medicine for exact dosing instructions. Take Phenobarbital by mouth with or without food.
Do not suddenly stop taking Phenobarbital or change the dose without checking with your doctor. If you miss a dose of Phenobarbital, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. **Do not take 2 doses at once.**

ASK YOUR HEALTH CARE PROVIDER ANY QUESTIONS YOU MAY HAVE ABOUT HOW TO USE PHENOBARBITAL. IMPORTANT SAFETY INFORMATION:

Phenobarbital may cause dizziness, drowsiness, or lightheadedness. These effects may be worse if you take it with alcohol or certain medicines. Use Phenobarbital with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it.

Do not drink alcohol or use medicines that may cause drowsiness (eg, sleep aids, muscle relaxers) while you are using Phenobarbital; it may add to their effects. Ask your pharmacist if you have questions about which medicines may cause drowsiness.

Use Phenobarbital with caution in the ELDERLY; they may be more sensitive to its effects.

Phenobarbital should not be used in **CHILDREN younger than 12 years old; safety and effectiveness in these children have not been confirmed.**

Hormonal birth control (eg, birth control pills) may not work as well while you are using Phenobarbital. To prevent pregnancy, use an extra form of birth control (eg, condoms).

PREGNANCY and BREAST-FEEDING: Phenobarbital has been shown to cause harm to the fetus. If you think you may be pregnant, contact your doctor. You will need to discuss the benefits and risks of using Phenobarbital while you are pregnant. Phenobarbital is found in breast milk. If you are or will be breast-feeding while you use Phenobarbital, check with your doctor. Discuss any possible risks to your baby.

When used for long periods of time or at high doses, Phenobarbital may not work as well and may require higher doses to obtain the same effect as when originally taken. This is known as TOLERANCE. Talk with your doctor if Phenobarbital stops working well. Do not take more than prescribed.

Some people who use Phenobarbital for a long time may develop a need to continue taking it. People who take high doses are also at risk. This is known as DEPENDENCE or addiction. If you stop taking Phenobarbital suddenly, you may have WITHDRAWAL symptoms. These may include anxiety, nausea, sleeplessness, and body aches.
Possible side effects of Phenobarbital:

All medicines may cause side effects, but many people have no, or minor side effects. Check with your doctor if any of these most COMMON side effects persist or become bothersome:

Clumsiness; dizziness; drowsiness; excessive daytime drowsiness ("hangover effect"); feeling of a whirling motion; headache; lightheadedness; nausea; tired feeling; vomiting; weak bones.

Seek medical attention right away if any of these SEVERE side effects occur:

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); confusion; difficulty sleeping; fainting; intense pain; very slow breathing.

OTHER DETAIL INFORMATION :

Phenobarbital, a long-acting barbiturate, is a central nervous system depressant. In ordinary doses, the drug acts as a sedative and anticonvulsant. Its onset of action occurs **within 30 minutes,** and the duration of **action ranges from 5 to 6 hours. It is detoxified in the liver.**

Phenobarbital is indicated for use as a sedative or anticonvulsant.

Phenobarbital is contraindicated in patients who are hypersensitive to barbiturates. In such patients, severe hepatic damage can occur from ordinary doses and is usually associated with dermatitis and involvement of parenchymatous organs. A personal or familial history of acute intermittent porphyria represents one of the few absolute contraindications to the use of barbiturates. Phenobarbital is also contraindicated in patients with marked impairment of liver function, or respiratory disease in which dyspnea or obstruction is evident. It should not be administered to persons with known previous addiction to the sedative/hypnotic group, since ordinary doses may be ineffectual and may contribute to further addiction.

IN SMALL DOSES, THE BARBITURATES MAY INCREASE THE REACTION TO PAINFUL STIMULI. TAKEN BY THEMSELVES, THE BARBITURATES CANNOT BE RELIED UPON TO RELIEVE PAIN OR EVEN TO PRODUCE SEDATION OR SLEEP IN THE PRESENCE OF SEVERE PAIN.

Barbiturates induce liver microsomal enzyme activity. This accelerates the biotransformation of various drugs and is probably part of the mechanism of the tolerance encountered with barbiturates. Phenobarbital, therefore, should be used with caution in patients with decreased liver function. This drug should also be administered cautiously to patients with a history of drug dependence or abuse **(see DRUG ABUSE AND DEPENDENCE).**

Phenobarbital may decrease the potency of coumarin anticoagulants; therefore, patients receiving such concomitant therapy should have more frequent prothrombin determinations. As with other sedatives and hypnotics, elderly or debilitated patients may react to barbiturates with marked excitement, depression, or confusion.

The systemic effects of exogenous hydrocortisone and endogenous hydrocortisone (cortisol) may be diminished by phenobarbital. Thus, this product should be administered with caution to patients with borderline hypoadrenal function, regardless of whether it is of pituitary or of primary adrenal origin.

Phenobarbital may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery.
The patient should be cautioned accordingly.

Phenobarbital in combination with alcohol, tranquilizers, and other central nervous system depressants has additive depressant effects, and the patients should be so advised. Patients taking this drug should be warned not to exceed the dosage recommended by their physician. Toxic effects and fatalities have occurred following overdoses of phenobarbital alone and in combination with other central nervous system depressants. Caution should be exercised in prescribing unnecessarily large amounts of phenobarbital for patients who have a history of emotional disturbances or suicidal ideation or who have misused alcohol and other **CNS drugs (see OVERDOSAGE).**

Pregnancy Category B – Reproduction studies have been performed in animals and have revealed no evidence of impaired fertility or harm to the fetus due to phenobarbital. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Caution should be exercised when phenobarbital is administered to a nursing woman.

The following adverse reactions have been reported:

Residual sedation or “hangover”, drowsiness, lethargy, and vertigo. Emotional disturbances and phobias may be accentuated. In some persons, barbiturates such as phenobarbital repeatedly produce excitement rather than depression, and the patient may appear to be inebriated. Like other nonanalgesic hypnotic drugs, barbiturates, such as phenobarbital, when given in the presence of pain, may cause restlessness, excitement, and even delirium. **Rarely, the use of barbiturates results in localized or diffused myalgic, neuralgic, or arthritic pain, especially in psychoneurotic patients with insomnia.** The pain may appear in paroxysms, **is most intense in the early morning hours,** and is mot frequently located in the region of the neck, should girdle, and upper limbs. Symptoms may last for days after the drug is discontinued.

Respiratory depression, apnea, circulatory collapse.

Acquired hypersensitivity to barbiturates consists chiefly in allergic reactions that occur especially in persons who tend to have asthma, urticaria, angioedema, and similar conditions. Hypersensitivity reactions in this category include localized swelling, particularly of the eyelids, cheeks, or lips, and erythematous dermatitis. Rarely, exfoliative dermatitis (e.g., Stevens-Johnson syndrome and toxic epidermal necrolysis) may be caused by phenobarbital and can prove fatal. The skin eruption may be associated with fever, delirium, and marked degenerative changes in the liver and other parenchymatous organs. In a few cases, megaloblastic anemia has been associated with the chronic use of phenobarbital.

Nausea and vomiting; headache.

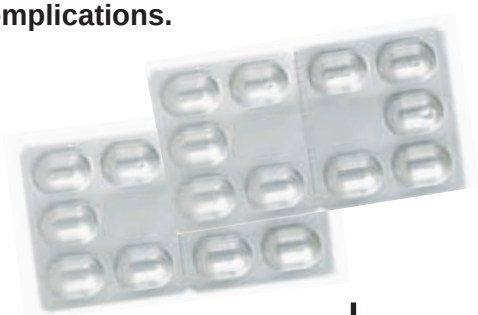
Controlled Substance – Phenobarbital is a Schedule IV drug.

Prolonged, uninterrupted use of barbiturates (particularly the short-acting drugs), even in therapeutic doses, may result in psychic and physical dependence. Withdrawal symptoms due to physical dependence following chronic use of large doses of barbiturates may include delirium, convulsions, and death.

The signs and symptoms of barbiturate poisoning are referable especially to the central nervous system and the cardiovascular system. Moderate intoxication resembles alcoholic inebriation. In severe intoxication, the patient is comatose, the level of reflex activity conforming in a general way to the intensity of the central depression. The deep reflexes may persist for some time despite coexistent coma. The Babinski sign is often positive. **The EEG may be of the “burst-suppression” type, with brief periods of electrical silence.** The pupils may be constricted and react to light, but late in the courage of barbiturate poisoning they may show hypoxic paralytic dilatation. Respiration is affected early. Breathing may be either slow or rapid and shallow; Cheyne-Stokes rhythm may be present. Respiratory minute volume is diminished, and hypoxia and respiratory acidosis may develop. The blood pressure falls, owing partly to depression of medullary vasomotor centers; partly to a direct action of the drug on the myocardium, sympathetic ganglia, and vascular smooth muscle; partly to hypoxia.

The patient thus **develops a typical shock syndrome, with a weak and rapid pulse, cold and clammy skin, and a rise in the hematocrit.** Respiratory complications (atelectasis, pulmonary edema, and bronchopneumonia) and renal failure are much dreaded and not infrequent concomitant of severe barbiturate poisoning. There is usually hypothermia, **sometimes with temperatures as low as 32°C.**

General management should consist of symptomatic and supportive therapy, including gastric lavage, administration of intravenous fluids, and maintenance of blood pressure, body temperature and adequate respiratory exchange. Dialysis will increase the rate of removal of barbiturates from the body fluids. Antibiotics may be required to control pulmonary complications.



Oral Sedative Dose, Adults – 30 to 120 mg daily in 2 or 3 divided doses. Children – 6 mg/kg of body weight daily in 3 divided doses.
Oral Hypnotic Dose, Adults – 100 to 320 mg.
Oral Anticonvulsant Dose, Adults – 50 to 100 mg 2 or 3 times daily.
Children – 15 to 50 mg 2 or 3 times daily.
Phenobarbital Tablets USP 15 mg: White, round, unscored, compressed tablet imprinted “West-ward 445”.
Bottles of 1000 tablets.
Phenobarbital Tablets USP 30 mg: White, round, scored, compressed tablet imprinted “West-ward 450”.
Bottles of 1000 tablets.
Bottles of 5000 tablets.
Phenobarbital Tablets USP 60 mg: White, round, unscored, compressed tablet imprinted “WW-455”.
Bottles of 100 tablets. Bottles of 1000 tablets.
Phenobarbital Tablets USP 100 mg: White, round, scored, compressed tablet imprinted “WW-458”.
Bottles of 100 tablets. Bottles of 1000 tablets.
Store at 20-25°C (68-77°F) [See USP Controlled Room Temperature]. Protect from light and moisture.

Dispense in a tight, light-resistant container as **defined in the USP using a child-resistant closure**

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