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Epiphen 30 mg and 60 mg Tablets

Species:	Dogs
Therapeutic indication:	**Pharmaceuticals: Neurological preparations:** Others
Active ingredient:	Phenobarbital
Product:	Epiphen 30 mg and 60 mg Tablets
Product index:	Epiphen Tablets

Presentation

Tablets for oral administration.

Phenobarbital tablets are available in two strengths:

White, circular biconvex tablets plain on both sides containing 30 mg phenobarbital.

White, embossed, circular, biconvex tablets containing 60 mg phenobarbital.

Uses

Phenobarbital is an antiepileptic, for use in the control of epilepsy in dogs.

Dosage and administration

The required dosage will differ to some extent between individuals and with the nature and severity of the disorder.

Dogs should be dosed orally, starting with a dose of 2–5 mg per kg bodyweight per day. The dose should be divided and administered twice daily.

Steady state serum concentrations are not reached until 1–2 weeks after treatment is initiated. The full effect of the medication does not appear for two weeks and doses should not be increased during this time.

If seizures are not being controlled, the dosage may be increased by 20% at a time, with associated monitoring of serum phenobarbital levels. The phenobarbital serum concentration may be checked after steady state has been achieved, and if it is less than 15 microgram/ml the dose may be adjusted accordingly. If seizures recur the dose may be raised up to a maximum concentration of 45 microgram/ml. High plasma concentrations may be associated with hepatotoxicity. Blood samples could be taken at the same time to allow plasma phenobarbital concentrations to be determined preferably during trough levels, shortly before the next dose of phenobarbital is due.

Tablets are not intended to be subdivided. For accuracy of dosing, dogs less than 12kg should commence therapy with Epiphen Solution.

Contra-indications, warnings, etc

Contra-indications

Not for use in pregnant animals. Do not administer to animals with impaired hepatic function.

Special precautions for use in animals

Withdrawal of phenobarbital or transition to or from another type of antiepileptic therapy should be made gradually to avoid precipitating an increase in the frequency of seizures.

Phenobarbital may reduce the activity of some drugs by increasing the rate of metabolism through induction of drug-metabolising enzymes in liver microsomes.

Use of phenobarbital tablets in conjunction with primidone is not recommended as primidone is predominantly metabolised to phenobarbital.

Smaller quantities dispensed from this bulk pack should be supplied in a container with a child resistant closure.

User Warnings

In case of accidental ingestion seek medical attention immediately advising medical services of barbiturate poisoning. Wash hands thoroughly after use.

Adverse Reactions

Occasionally polyphagia, polyuria and polydipsia have been reported, but these effects are usually transitory and disappear with continued medication.

Toxicity may develop at doses over 20 mg/kg/day or when serum phenobarbital levels rise above 45 microgram/ml.

In the light of isolated reports describing hepatotoxicity associated with combination anticonvulsant therapy, it is recommended that:

1. Hepatic function is evaluated prior to initiation of therapy (e.g. measurement of serum bile acids).
2. Therapeutic phenobarbital serum concentrations are monitored to enable the lowest effective dose to be used. Typically concentrations of 15–45 microgram/ml are effective in controlling epilepsy.
3. Hepatic function is re-evaluated on a regular (6 to 12 month) basis.
4. Seizure activity is re-evaluated on a regular basis.

Use during pregnancy or lactation

In humans, mothers receiving antiepileptic medication have a 6 to 10% incidence of significant abnormality in their offspring. Neonatal sedation and drug dependence may occur if given close to term. Phenobarbital crosses the placental barrier and small amounts are excreted in breast milk. For these reasons, phenobarbital is contraindicated in pregnancy and nursing bitches.

Interaction with other medicinal products and other forms of interaction

Phenobarbital will potentially reduce therapeutic levels of a wide range of drugs due to its inducing effect on hepatic enzymes.

Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdosage may result in coma, severe respiratory and cardiovascular depression, hypotension and shock leading to renal failure and death. Following the recent ingestion of an overdose, the stomach may be emptied by lavage. The prime objectives of management are then intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of cardiovascular, respiratory and renal functions and to the maintenance of the electrolyte balance.

Withdrawal period

Not applicable

Pharmaceutical precautions

Do not store above 25°C. Protect from light. Store in a dry place and replace the closure promptly.

Any unused product must be destroyed in accordance with the Misuse of Drugs Regulations (2001). Any waste material should be disposed of in accordance with local requirements.

Legal category

Legal category: POM-V

Legal category description: CD(Sch 3)

Packaging quantities

Polypropylene tubes with low density polyethylene caps or high density polyethylene jar securitainer and polypropylene lid containing a dessiccant (silica gel). Pack size 1000 tablets.

Further information

The antiepileptic effects of phenobarbital are probably the result of at least two mechanisms: - Decreased monosynaptic transmission, which presumably results in reduced neuronal excitability and an increase in the motor cortex's threshold for electrical stimulation.

After oral administration of phenobarbital to dogs, the drug is rapidly absorbed and maximal plasma concentrations are reached within 4 - 8 hours. Bioavailability is between 86% - 96%. About 45% of the plasma concentration is protein bound. Metabolism is by aromatic hydroxylation of the phenyl group in the para position, and about one third of the drug is excreted unchanged in the urine. Elimination half-lives vary considerably between individuals and range from about 40 - 90 hours.

Marketing Authorisation Number

Epiphen 60 mg tablets:Vm 08007/4066

Epiphen 30 mg tablets:Vm 08007/4067

Significant changes

GTIN

GTIN description:	Epiphen 30mg tablet
GTIN:	03605874237575
GTIN description:	Epiphen 60mg tablet
GTIN:	03605874237629