

## Epiphen Tablets (Vétoquinol UK Limited)

**Epiphen Tablets**  
b6f Phenobarbital

**Presentation:**

Tablets for oral administration.

Phenobarbital tablets are available in two strengths:

White circular biconvex tablets containing 30 mg Phenobarbital PhEur.

Pale orange circular biconvex tablets containing 60 mg Phenobarbital PhEur. 60mg tablets also contain Sunset Yellow (E110) 0.05mg per tablet.

**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 should 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 and nursing bitches.

Do not administer to animals with impaired hepatic function.

**Warnings:**

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

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

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.

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.

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.

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

**Operator safety:**

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

**Pharmaceutical precautions:**

Do not store above 25°C. Protect from light

Unused product and containers should be disposed of in accordance with national requirements.

**Legal category:**

POM CD (Sch 3).

**Package quantities:**

Polypropylene tubes with low density polyethylene caps containing 1000 tablets.

**Further information:**

Nil.

**Marketing authorisation numbers:**

Epiphen 60 mg tablets: VM 08007/4066

Epiphen 30 mg tablets: VM 08007/4067