

Epiphen Solution (Vétoquinol UK Limited)

Epiphen Solution
b6f Phenobarbital

Presentation:

Solution containing 4% Phenobarbitone PhEur (INN = phenobarbital).

Uses:

Phenobarbitone is an antiepileptic agent for use in the control of epilepsy in the dog.

Dosage and administration:

| Weight of dog | 30ml bottle | 100ml bottle |
|---------------|--------------------|---------------------|
| 2kg | 4-7 drops per day | 0.15-0.25ml per day |
| 5kg | 8-16 drops per day | 0.30-0.60ml per day |
| 10kg | ----- | 0.65-1.25ml per day |
| 15kg | ----- | 0.95-1.90ml per day |
| 20kg | ----- | 1.30-2.50ml per day |
| 30kg | ----- | 1.90-3.75ml per day |
| 40kg | ----- | 2.50-5.00ml per day |

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 phenobarbitone levels. The phenobarbitone 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 serum 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 phenobarbitone concentration to be determined preferably during trough levels shortly before the next dose of phenobarbitone is due.

Contra-indications warnings etc:

Not for use in pregnant animals or nursing bitches.

Do not administer to animals with impaired hepatic function.

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 20mg/kg/day or when serum phenobarbitone 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 phenobarbitone serum concentrations are monitored to enable the lowest effective dose to be used. Typically concentrations of 15 - 45microgram/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 phenobarbitone 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 phenobarbitone in conjunction with primidone is not recommended as primidone is predominantly metabolised to phenobarbitone.

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

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 periods:

Not applicable

Operator warnings:

In case of accidental ingestion seek medical attention immediately advising medical services of barbiturate poisoning or show this container.

Flammable keep away from sources of ignition. Do not smoke.

Wash hands after use.

Pharmaceutical precautions:

Store below 25°C.
Protect from light.
Keep out of reach of children.
Keep container tightly closed
Dispose of in accordance with local authority regulations.

Legal category:

POM CD (Sch3)

Package quantities:

30ml amber type III glass bottle with integral LDPE dropper and Child Resistant Closure: 100ml high density polyethylene bottle with integral syringe adapter insert and child resistant closure.

Further information:

The antiepileptic effects of phenobarbitone 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 phenobarbitone 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.

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