SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Epiphen 60 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient: 60 mg of Phenobarbital per tablet

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet
White, circular bioconvex tablet with stamp '60' on surface.

4. CLINICAL PARTICULARS

4.1 Target species

Dog

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. 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.

obarbital tablets in conjunction with primidone is not

recommended as primidone is predominantly metabolized to phenobarbital.

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

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental ingestion, seek medical attention immediately advising medical services of barbiturate poisoning.

Wash hands thoroughly after use.

4.6 Adverse reactions (frequency and seriousness)

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 phenobarbital levels rise above 45µg/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 15-45µg/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.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

be administered and administration route

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 2-5mg 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 15µg/ml the dose may be adjusted accordingly. If seizures recur the dose may be raised up to a maximum serum concentration of 45µg/ml. High plasma concentrations may be associated with hepatotoxicity. Blood samples could be taken at the same time to allow plasma phenobarbital concentration to be determined preferably during trough levels, shortly before the next dose of phenobarbital is due.

For accuracy of dosing, dogs under 12 kg should commence therapy with Epiphen solution.

Tablets are not intended to be subdivided.

4.9 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.

4.10 Withdrawal period(s)

N/A.

5. PHARMACOLOGICAL PROPERTIES

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.
:y 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other Substances
Lactose Monohydrate
Sodium Starch Glycolate
Sodium Lauryl Sulphate
Stearic Acid
Magnesium Stearate
Pregelatinised Starch

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4. Special precautions for storage

Do not store above 25◦C.

Protect from light.

Store in a dry place and replace the closure promptly.

6.5 Nature and composition of immediate packaging

White, circular, biconvex tablets (6.5mm diameter) for oral administration packed in polypropylene (PP) tubes with low density polyethylene (LDPE) caps or high density polyethylene (HDPE) jar securitainer and polypropylene (PP) lid containing a desiccant (silica gel).

Pack size: 1,000 tablets.

Printed outer carton also containing a product insert.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
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8. MARKETING AUTHORISATION NUMBER

Vm 08007/4066

9. DATE OF FIRST AUTHORISATION

11 April 1996

10. DATE OF REVISION OF THE TEXT

May 2018

Approved: 02 May 2018

D Austin