PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 50mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each orange film-coated tablet contains 50 mg propentofylline (3-methyl-1(5-oxohexyl)-7-propylxanthine).

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

2x30 tablets

5. TARGET SPECIES

For Dogs

6. INDICATION(S)

Uses: For improvement in dullness, lethargy and overall demeanour in older dogs. May increase willingness to exercise.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Must be given at least 30 minutes before food.

For uses, dosage, administration, contra-indications, warnings and disposal advice, see package leaflet.

Divide the tablets in halves and quarters with a knife or with a tablet splitter.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

For uses, dosage, administration, contra-indications, warnings and disposal advice, see package leaflet.

10. EXPIRY DATE

EXP END OF:

11. SPECIAL STORAGE CONDITIONS

Keep blister packs in outer carton.

Do not store above 25°C.

Store in a dry place.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

For uses, dosage, administration, contra-indications, warnings and disposal advice, see package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 06376/4074

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 50mg tablets

Propentofylline 50 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International BV

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Vm 06376/4074

PACKAGE LEAFLET FOR:
Vivitonin 50mg tablets

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 50mg tablets

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Presentation

Orange-yellow, film-coated tablets quarter-scored on one side.

Each tablet contains 50 mg of the xanthine derivative 3-methyl-1-(5-oxohexyl)- 7-propylxanthine (Propentofylline).

4. INDICATION(S)

Uses

For improvement in dullness, lethargy and overall demeanour in dogs. Vivitonin is particularly useful in older dogs, where it may increase willingness to exercise and exercise tolerance.

The active ingredient, propentofylline, has been shown to increase blood flow, particularly of the heart and skeletal muscle. It also increases the blood flow of the brain and therefore its oxygen supply, without increasing the brain’s glucose demand.

Propentofylline has a modest positive chronotropic effect and a marked positive inotropic effect. In addition it has been shown to have an antiarrhythmic effect in dogs with myocardial ischemia and a bronchodilator action equivalent to that of aminophylline.
Propentofylline inhibits platelet aggregation and improves the flow properties of erythrocytes. It has a direct effect on the heart and reduces peripheral vascular resistance thereby lowering cardiac load.

5. CONTRAINDICATIONS

Contra-indications, warnings, etc.

Not to be administered to pregnant bitches or breeding animals.

Do not use in animals with known hypersensitivity to the active substance or any of the excipients.

6. ADVERSE REACTIONS

In section: Contra-indications, warnings, etc.

Vomiting has been observed on rare occasions, particularly at the commencement of therapy. Symptoms of cardiac and cerebral overstimulation have been observed. In such cases, animals should be treated symptomatically.

In rare cases allergic reactions (e.g. urticaria) may occur and these necessitate discontinuation of the treatment.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)

- common (more than 1 but less than 10 animals in 100 animals)

- uncommon (more than 1 but less than 10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

7. TARGET SPECIES

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and administration

Half a tablet per 5 kg body weight twice a day.

Dogs of less than 5 kg may receive a quarter of a tablet twice a day.

Dogs of more than 20 kg can be given Vivitonin® 100 mg tablets. Divide the tablets in halves and quarters with a knife or with a tablet splitter.

The tablets can be administered directly onto the back of the dog's tongue or can be mixed in a small ball of food and should be administered at least 30 minutes before feeding.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions

Do not store above 25°C.

Store in a dry place.

Keep blister packs in outer carton.

12. SPECIAL WARNING(S)

In section: Contra-indications, warnings, etc.

Specific diseases (e.g. kidney disease) should be treated accordingly.

In the case of renal failure, the dose should be reduced.

Consideration should be given to rationalising the medication of dogs already receiving treatment for congestive heart failure or bronchial disease.

Operator warnings:

Care should be taken to avoid accidental ingestion.

Wash hands after use.

Keep out of the reach and sight of children.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of empty packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

For animal treatment only

Legal category

POM-V

To be supplied only on veterinary prescription.

Package quantities

Packs of 2 x 30 tablets

Further information

Nil.

Marketing authorisation number

Vm 06376/4074

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park
Citywest Road, Dublin 24

Marketing Authorisation Holder:

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

Approved 28 June 2024
Gavin Hall