PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 100mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 100 mg propentofylline.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

6x10 tablets

5. TARGET SPECIES

For Larger 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.

Tablets should not be quartered.

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

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

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

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in a dry place.

Keep blister packs in outer carton.

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

MSD Animal Health UK Limited, Walton Manor,

Walton, Milton Keynes MK7 7AJ

Licensed distributor for Northern Ireland

Intervet Ireland Ltd., Magna Drive, Magna

Business Park, Citywest Road, DUBLIN 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4446

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 100mg tablets

Propentofylline 100 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Vm 01708/4417

PACKAGE LEAFLET FOR:

Vivitonin 100mg tablets

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vivitonin 100mg tablets

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

Presentation

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

Each tablet contains 100 mg of the xanthine derivative, Propentofylline.

4. INDICATION(S)

Uses

For improvement in dullness, lethargy and overall demeanour in larger 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 10 kg body weight twice a day.

Vivitonin 100 mg tablets should not be quartered. More accurate dosing may be achieved using a combination of Vivitonin 100 mg and Vivitonin 50 mg tablets. Dogs of less than 20 kg can be given Vivitonin 50 mg tablets. Divide the tablets in halves 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. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Date of preparation

April 2021

15. OTHER INFORMATION

For animal treatment only

Legal category

POM-V

To be supplied only on veterinary prescription.

Package quantities

Packs of 6 x 10 tablets

Further information

Nil.

Marketing authorisation number

Vm 01708/4446

Licensed distributor for Northern Ireland

Intervet Ireland Ltd.,

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

Marketing Authorisation Holder:

MSD Animal Health UK Ltd.

Walton Manor, Walton,

Milton Keynes, Buckinghamshire

MK7 7AJ

Approved: 01/04/21