PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NATURE/TYPE: Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Corvental-D 500 mg Hard Capsules

2. STATEMENT OF ACTIVE SUBSTANCES

Active ingredient: Each capsule contains 500 mg Theophylline in a sustained release form.

3. PHARMACEUTICAL FORM

Hard capsules

4. PACKAGE SIZE

100 capsules
500 mg

5. TARGET SPECIES

Dog

6. INDICATION(S)

For the treatment of bronchitis and congestive heart failure in the dog.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: 20 mg per kg bodyweight to be administered orally once daily.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet.

10. EXPIRY DATE

USE BY END: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

Store in a dry place.
Keep blisters in outer carton.

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

See package leaflet.

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

For animal treatment only. 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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4016
POM-V

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE: Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Corvental-D Hard Capsules Theophylline 500 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

{month/year}

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Corvental-D Hard Capsules

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

Marketing authorisation holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Tel: 01256 353131

Manufacturer responsible for batch release:
Swiss Caps GmbH
Grassingerstraße 9
83043 Bad Aibling
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Corvental-D Capsules 100 mg Hard Capsules
Corvental-D Capsules 200 mg Hard Capsules
Corvental-D Capsules 500 mg Hard Capsules

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

Corvental-D Hard Capsules are hard gelatin capsules containing 100 mg, 200 mg or 500 mg Theophylline in a sustained release “Divido” presentation. The capsules are coloured and sized, according to active ingredient content.

Corvental-D Capsules 100 mg Hard Capsules: blue/white, size 3, “Th100” written in black.
Corvental-D Capsules 200 mg Hard Capsules: opaque green/transparent green, size 2, “Th200” written in white.
Corvental-D Capsules 500 mg Hard Capsules: opaque green/transparent green, size 0/elongated, “Th500” written in white.

4. INDICATION(S)

For the treatment of bronchitis and congestive heart failure in the dog.

5. CONTRAINDICATIONS

Do not use in dogs with a known history of epileptiform seizures as convulsions have been reported in patients on theophylline treatment, often with no preceding signs of toxicity and in otherwise apparently normal animals.

Concurrent use of beta sympathomimetics is contra-indicated, as additive or synergistic interactions resulting in exaggerated side effects may result.

6. ADVERSE REACTIONS

The following side effects have been reported; restlessness, agitation, excitement, vomiting, diarrhoea, polydipsia, sedation, reduced appetite and polyuria. If vomiting occurs the dose should be reduced or the treatment discontinued.
If signs of CNS excitement occur (twitching, restlessness or convulsions) discontinue treatment immediately.

7. TARGET SPECIES

Dog

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

20 mg per kg bodyweight to be administered orally once daily.

9. ADVICE ON CORRECT ADMINISTRATION

For animal treatment only.
Care should be taken to ensure that dogs are weighed carefully and accurately, and the dose does not exceed 20 mg/kg bodyweight.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Do not store above 30°C.
Store in a dry place. Keep blisters in outer carton.
Do not use after the expiry date stated on the carton or blister after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Theophylline should be used with caution in patients with liver disease.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
When theophylline is prescribed to pregnant bitches, the risk benefit of the treatment should be assessed. Only small amounts of theophylline are excreted in milk.

Interaction with other medicinal products and other forms of interaction:
Plasma theophylline levels may increase in patients under treatment with macrolide & fluoroquinolone antibiotics such as erythromycin & enrofloxacin, and decrease in patients receiving phenobarbitone or phenytoin.
Theophylline may reduce the convulsive threshold in patients receiving ketamine.
Administration of theophylline shortly before halothane anaesthesia may result in arrythmogenic effects.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

POM-V
To be supplied only on veterinary prescription only.

Packs containing 100 capsules are available for all 3 strengths.
The capsules are packed in blister strips.
100 mg capsules - Vm 00879/4014
200 mg capsules - Vm 00879/4015
500 mg capsules - Vm 00879/4016

Approved 16 October 2020