

**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 contraindicated, 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 arrhythmogenic 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