

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Corvental D 100 mg
Hard Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition (per capsule)

Active ingredient:

Theophylline 100 mg

Excipients:

Indigotine (E132), as colorant 0.048 mg

Titanium dioxide (E171), as colorant 1.152 mg

Ferric oxide (E172) 0.25 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard.

Opaque blue/opaque white coloured capsules, size 3. Each capsule half is printed in black with "Th100".

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

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.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i. Special precautions for use in animals

Theophylline should be used with caution in patients with liver disease. If vomiting occurs, the dose should be reduced or the treatment discontinued.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

The following side effects have been reported: restlessness, agitation, excitement, vomiting, diarrhoea, polydipsia, sedation, reduced appetite and polyuria.

If signs of CNS excitement occur, (twitching, restlessness or convulsions) discontinue treatment immediately.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

Plasma theophylline levels may increase in patients under treatment with macrolide and fluoroquinolone antibiotics, such as erythromycin and 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.

4.9 Amounts to be administered and administration route

20 mg per kg bodyweight to be given orally once daily only.

Care should be taken to ensure that dogs are weighed carefully and accurately, and the dose does not exceed 20 mg/kg body weight.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

There is no specific treatment for theophylline overdose in the dog. The condition should be treated symptomatically with emetics, oral activated charcoal or anti-convulsive drugs as necessary.

4.11 **Withdrawal period(s)**

Not applicable.

5. **PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Systemic drugs for obstructive airway diseases, xanthines.

ATCvet code: QR03DA04

5.1 **Pharmacodynamic properties**

Theophylline is a dimethylated xanthine which was introduced into medicine in 1900. It is similar in structure to the common dietary xanthines, caffeine and theobromine, and has many pharmacological actions. It relaxes smooth muscle, relieves bronchospasm and has a stimulant effect on respiration. Theophylline dilates coronary arteries and increases the strength of contraction of the myocardium. It also acts on the kidney to induce diuresis and is a potent stimulant of the central nervous system.

5.2 **Pharmacokinetic particulars**

Absorption: The methylxanthines are readily absorbed following oral administration. Studies in man have shown that the administration of theophylline with food may slow but not reduce absorption of the drug, and help avoid local irritation of the gastro-intestinal tract. In the absence of food, theophylline solutions or uncoated tablets produce maximal plasma concentration within two hours. The rate and extent of absorption of theophylline differs between various slow release formulations and absorption of the drug appears to be slower at night. However, slow release formulations, if completely absorbed, allow longer dosing intervals with less fluctuation in serum concentration.

Distribution: Theophylline is distributed into all body compartments and human studies have shown that it crosses the placenta and diffuses into breast milk. The drug also crosses the blood brain barrier and enters the central nervous system. The apparent volume of distribution of theophylline in man ranges from 300 to 700 ml/kg and in dogs, 500 to 800 ml/kg. In humans, it is about 50% bound to plasma proteins, but in dogs is lower at about 9%.

Metabolism and Excretion: Little information is available concerning the metabolism and excretion of theophylline in dogs. In man, theophylline is eliminated from the body by hepatic biotransformation into relatively inactive metabolites which are excreted in the urine. Theophylline is metabolised by demethylation and oxidation, mainly to 1,3-dimethyluric acid. D-methyluric acid and 3-methylxanthine are also formed in smaller amounts, and about 10% of the drug is excreted unchanged in the urine. The half life of theophylline in adults is 8 to 9 hours, and in children it is 3.5 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K-25
Silica Colloidal Anhydrous
Triethyl citrate
Poly (Ethylacrylate, Methylmethacrylate, trimethylammonio Ethylmethacrylate Chloride) 1:2:0.1 150,000 (Eudragit RS 100)
Poly (Ethylacrylate, Methylmethacrylate, trimethylammonio Ethylmethacrylate Chloride) 1:2:0.2 150,000 (Eudragit RL 100)
Talc purified

Capsule cap

Titanium dioxide (E171)
Indigotine (E132)
Gelatin
Water, purified

Capsule body

Titanium dioxide (E171)
Gelatin
Water, purified

Printing Ink

Ferric oxide (E172)
Shellac
Soya lecithin (E322)

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 30°C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Cartons containing 3 or 5 PVC blister strips with aluminium foil seal.
Each blister strip contains 20 capsules.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
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Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4014

9. DATE OF FIRST AUTHORISATION

16 February 1993

10. DATE OF REVISION OF THE TEXT

October 2020

Approved 16 October 2020

