SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HyperCard 10 mg Coated Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance	Quantitative composition
Diltiazem	9.20 mg (equivalent to 10 mg of Diltiazem hydrochloride)
Excipients	
Tartrazine (E102)	0.11 mg
Titanium dioxide (E171)	1.1 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet.
A yellow coated biconvex tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the therapeutic treatment of feline primary hypertrophic cardiomyopathy.

4.3 Contraindications

Do not use in animals suffering from AV block (2^{nd} or 3^{rd}), hypotension or sick sinus syndrome.
Diltiazem should not be given to animals suffering from hepatic disease.
Do not use in animals suffering from renal disease.
Do not use in cats less than 12 months old.
Do not use in cats weighing less than 3 kg.
Do not use in animals that are hypersensitive to Diltiazem.
Do not use in cats with severe bradycardia or arterial hypotension.
Do not use in conjunction with β blockers, digitalis or digoxin.
Do not use in pregnant or lactating females.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Hepatic failure may increase the plasma concentration of diltiazem.
Monitor glucose levels carefully in diabetic animals.
Use with caution in cats suffering from congestive heart failure.
Cats with possible pre-existing thyroid problems or hyperthyroidism should be treated for this first and then reassessed prior to commencing treatment with Diltiazem.
Clinical examination to assess the effectiveness of treatment should be performed after 8 weeks.
Cardiac rate should be monitored prior to treatment commencing and at every follow up visit.

i. Special precautions for the person administering the veterinary medicinalproduct to animals

Wash hands after use as tartrazine, in the colour coating may cause allergic reaction in people who are susceptible.
In the case of accidental ingestion, seek medical advice immediately and show the package insert to the physician.
Do not break tablets.

4.6 Adverse reactions (frequency and seriousness)

Some lethargy can occur at the beginning of treatment.
Diltiazem may cause gastrointestinal problems e.g. constipation, vomiting and anorexia.
Rashes, skin reactions and erythema are potential side effects of diltiazem.
Bradycardia, dyspnoea, hypotension and conduction abnormalities may occasionally occur. In such cases treatment should be suspended.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating females. Studies in laboratory animals have shown evidence of teratogenic and embryotoxic effects.

4.8 Interaction with other medicinal products and other forms of interaction

Use with caution in conjunction with other calcium channel blockers, anticonvulsant drugs, immunosuppressant drugs, lithium, neuromuscular blocking agents and aminoglycoside antibiotics.
Concurrent use with Cimetidine or any other Histamine 2 receptor antagonists may cause an increase in plasma Diltiazem concentrations.
Gaseous anaesthetics such as halothane, isoflurane or enflurane have synergistic or additive effects with Diltiazem, which may lead to hypotension, depressed myocardial contractile function, slow junctional rhythm and AV block. Therefore animals treated with Hypercard 10 mg and undergoing gaseous anaesthesia, should be monitored closely.

4.9 Amount(s) to be administered and administration route

Oral.
1 tablet per cat (weighing 3.0 - 6.25 kg bodyweight) every eight hours (equivalent to 1.6 - 3.3 mg diltiazem hydrochloride per kg every 8 hours).
Treatment should be given for the life of the animal.

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

Carry out gastric lavage and dose with activated charcoal.
For bradycardia and heart block, treat with normal saline infusion and vasopressors (Atropine, Dopamine or Isoprenaline).
Observations in humans have indicated that treatment with calcium may be useful in treating toxicity from calcium channel blocker overdose.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Diltiazem hydrochloride. Diltiazem hydrochloride is a benzothiazepine derivative, which acts as a calcium channel blocker.

ATC Vet Code: QC08DB01

5.1 Pharmacodynamic properties

This group of compounds exert their effect by interacting with the slow L-type calcium channels, thereby selectively inhibiting the inward movement of Ca ions across the cell membrane into vascular smooth muscle cells and myocardial cells.
With hypertrophic cardiomyopathy (HCM) the heart generally has a diminished capacity to restore low, resting levels of calcium during diastole. It appears that Diltiazem ameliorates HCM by decreasing calcium levels in the heart enabling proper relaxation of the muscle and halting or reversing the progression of the disease. It reduces cardiac work by moderating the heart rate and by reducing systemic vascular resistance thus reducing oxygen demand.

5.2 Pharmacokinetic properties

Diltiazem is rapidly absorbed following oral administration. Oral bioavailability in cats (71 %) is higher than in other species and is most likely to be the result of a reduced first pass effect. Following administration of Hypercard 10 mg to cats, the average time to obtain maximum plasma concentration (Tmax) is approximately 90 minutes, with only low levels remaining after eight hours. No effect of feeding was observed on the absorption of Diltiazem from the gastrointestinal tract. There is no evidence of accumulation. In most species, Diltiazem is metabolised by the liver and little of the unchanged drug is excreted in the urine.
Plasma protein binding in cats is 50 - 60 %.
Diltiazem is a significant hepatic microsomal enzyme inhibitor (especially of

CYP3A4) and, therefore, will affect the pharmacokinetics and consequently possibly

the efficacy and tolerance of some substances used in veterinary medicine (see 4.8).

5.3 Environmental properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine (E102)
Titanium dioxide, (E171)
Sodium methyl hydroxybenzoate (E219)
Microcrystalline cellulose
Lactose monohydrate
Maize starch
Magnesium stearate
Polyethylene glycol 4000
Povidone (K30)
Food grade shellac
Isopropanol
Sucrose
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the blister strips in the outer carton.

6.5 Nature and composition of immediate packaging

Tablets are located in a preformed low density polyethylene base containing 10 tablets and sealed with PC 100 laminate comprising of aluminium foil and a heat seal lacquer. Once sealed, 3 blisters of 10 tablets (30 tablets) are placed in a cardboard box.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
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Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4060

9. DATE OF FIRST AUTHORISATION

16 August 2000

10. DATE OF REVISION OF THE TEXT

October 2015

Approved: 14 October 2015