

HyperCard® 10 mg Coated Tablets for Cats

Species:Cats

Therapeutic indication:Pharmaceuticals: Cardiovascular and respiratory preparations

Active ingredient:Diltiazem Hydrochloride

Product:HyperCard® 10 mg Coated Tablets for Cats

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Qualitative and quantitative composition

Each tablet contains: Active substance:

Diltiazem 9.20 mg (equivalent to 10 mg of Diltiazem hydrochloride)

Excipients: Tartrazine (E102) 0.11 mg, Titanium dioxide (E171) 1.1 mg.

Pharmaceutical form

Coated tablet. A yellow coated biconvex tablet.

Clinical particulars

Target species

Cats.

Indications for use

For the therapeutic treatment of feline primary hypertrophic cardiomyopathy.

Contraindications

Do not use in animals suffering from AV block (2nd or 3rd), 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.

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.

Special precautions for the person administering the veterinary medicinal product to animals

Wash hands after use as tartrazine in the colour coating may cause allergic reaction in people who are susceptible.

In case of accidental ingestion, seek medical advice immediately and show the package insert to the physician.

Do not break tablets.

Adverse reactions

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.

Use during pregnancy and lactation

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

Interactions

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.

Amounts to be administered and administration route

Oral.

1 tablet per cat (weighing 3.0-6.25 kg body weight) 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.

Overdose

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.

Pharmacological particulars

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

ATCvet code: QC08DB01

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.

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 (T_{max}) 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 *Interactions*).

Pharmaceutical particulars

Shelf life

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

Special precautions for storage

Do not store above 25°C.

Keep the blister strips in the outer carton.

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.

Disposal

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

Marketing Authorisation Holder (if different from distributor)

Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom.

Marketing Authorisation Number

Vm 10434/4060

Significant changes

Date of the first authorisation or date of renewal

16 August 2000

Date of revision of the text

October 2015

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description:Hypercard 10 mg Coated Tablets for Cats:

GTIN:05055031400096

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