ANNEX I

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

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 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: QC 08 DB 01.

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).

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
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4060
IE: VPA 10799/016/001

9. RENEWAL OF THE AUTHORISATION

UK: 16 August 2000
IE: 18/04/2009

10. DATE OF REVISION OF THE TEXT

October 2015

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HyperCard 10 mg Coated Tablets for Cats
Diltiazem hydrochloride

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains:
Active substance:
10 mg of diltiazem hydrochloride
Excipients:

Tartrazine (E102)	0.11 mg
Titanium dioxide, (E171)	1.1 mg

3. PHARMACEUTICAL FORM

Coated tablets.

4. PACKAGE SIZE

30 tablets.

5. TARGET SPECIES

Cats.

6. INDICATION(S)

For the therapeutic treatment of feline primary hypertrophic cardiomyopathy.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral administration.
1 tablet per cat (weighing 3.0 - 6.25 kg body weight) every eight hours.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals suffering from AV block (2^{nd} or 3^{rd}), hypotension or sick sinus syndrome.
Do not use in 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.
See package insert for further details.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 10434/4060
IE: VPA 10799/016/001

17. MANUFACTURER'S BATCH NUMBER

Lot

18. FURTHER INFORMATION

UK: POM-V

IE: POM

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOIL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HyperCard 10 mg Coated Tablets for Cats
Diltiazem hydrochloride

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited - UK

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR
HyperCard 10 mg Coated Tablets for Cats

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

Marketing authorisation holder:
Dechra Limited, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.
Manufacturer:
Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton,
North Yorkshire, BD23 2RW, United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypercard 10 mg coated tablets for cats
Diltiazem hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:
Active substance:
Diltiazem hydrochloride 10 mg
Excipients:

Tartrazine (E102)	0.11 mg
Titanium dioxide (E171)	1.1 mg

Yellow coated biconvex tablets.

4. INDICATION

HyperCard 10 mg is indicated for the therapeutic treatment of feline primary hypertrophic cardiomyopathy.

5. 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.

6. 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.
If you notice any serious effects or any other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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

For oral administration.
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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use after the expiry date which is stated on the carton and blister after EXP.
Keep the blister strips in the outer carton.

12. SPECIAL WARNINGS

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 be reassessed prior to commencing treatment with diltiazem.
Clinical examination to assess the effectiveness of treatment should be performed after eight weeks.
Cardiac rate should be monitored prior to treatment commencing and at every follow up visit.

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

Interactions with other medicinal products:
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.

Overdosage:
In case of overdosage, 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.

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.
Do not break tablets.
In case of accidental ingestion, seek medical advice immediately and show the package insert to the physician.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2015

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

Presentation: 3 blisters of 10 tablets (30 tablets) in a cardboard box.

UK: Vm 10434/4060	POM-V	Prescription Only Medicine - Veterinarian

IE: VPA 10799/016/001	POM	Prescription Only Medicine

Veterinary medicinal product authorised for use in UK and IE.
Diltiazem hydrochloride is a benzothiazepine derivative which acts as a calcium channel blocker and exerts its effect by selectively inhibiting the inward movement of calcium ions across the cell membrane into vascular smooth muscle cells and myocardial cells.
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom