ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clomicalm 5 mg tablets for dogs
Clomicalm 20 mg tablets for dogs
Clomicalm 80 mg tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Clomipramine hydrochloride	5 mg (equivalent to 4.5 mg clomipramine)
Clomipramine hydrochloride	20 mg (equivalent to 17.9 mg clomipramine)
Clomipramine hydrochloride	80 mg (equivalent to 71.7 mg clomipramine)

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Microcristalline cellulose
Artificial meat flavour
Crospovidone
Povidone
Colloidal anhydrous silica
Magnesium stearate

5 mg tablet: Brownish-grey, oval-oblong, divisible. Scored on both sides.

20 mg tablet: Brownish-grey, oval-oblong, divisible. One side bears the imprint ‘C/G’, the other ‘G/N’ and scored on both sides.

80 mg tablet: Brownish-grey, oval-oblong, divisible. One side bears the imprint ‘I/I’, the other no imprint and scored on both sides.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

As an aid in the treatment of separation-related disorders in dogs manifested by destruction and inappropriate elimination (defaecation and urination) and only in combination with behavioural modification techniques.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to any of the excipients or to related tricyclic antidepressants.

Do not use in male breeding dogs.

3.4 Special warnings

The efficacy and safety of the veterinary medicinal product has not been established in dogs weighing less than 1.25 kg or under six months of age.

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is recommended that the veterinary medicinal product be administered to dogs with cardiovascular dysfunction or epilepsy with caution and only after an assessment of the benefit-risk ratio. Because of its potential anticholinergic properties, the veterinary medicinal product should also be used with care in dogs with narrow-angle glaucoma, reduced gastrointestinal motility or urinary retention. The veterinary medicinal product should be used under veterinary supervision.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In children, accidental ingestion should be regarded as serious. There is no specific antidote. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Overdose in human beings causes anticholinergic effects although central nervous and cardiovascular systems may also be affected. People with known hypersensitivity to clomipramine should administer the veterinary medicinal product with caution.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1,2], Diarrhoea Appetite disorder[2], Lethargy[2] Elevated liver enzymes[2] Convulsion, Mydriasis[4] Agression
Undetermined frequency (cannot be estimated from the available data):	Hepato-biliary disorder[3]

[1] May be reduced by co-administration of the veterinary medicinal product with a small quantity of food.
[2] Reversible when the veterinary medicinal product is discontinued.
[3] Especially with pre-existing conditions, and concurrent administrations of medicinal products metabolised via the hepatic system.
[4] Can also be observed following overdose.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy:
Laboratory studies in mice and rats have shown evidence of embryotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

Recommendations on the interaction between the veterinary medicinal product and other medicaments are derived from studies in species other than dogs. The veterinary medicinal product may potentiate the effects of the anti-arrhythmic medicinal products quinidine, anticholinergic agents (e.g. atropine), other central nervous system (CNS) medicinal products (e.g. barbiturates, benzodiazepines, general anaesthetics, neuroleptics), sympathomimetics (e.g. adrenaline) and coumarin derivatives. The administration of the veterinary medicinal product is not recommended in combination with, or within 2 weeks of therapy with monoamine oxidase inhibitors. Simultaneous administration with cimetidine may lead to increased plasma levels of clomipramine. Plasma levels of certain anti-epileptic medicinal products, such as phenytoin and carbamazepine, may be increased by co-administration with the veterinary medicinal product.

3.9 Administration routes and dosage

Oral use.

The veterinary medicinal product should be administered orally at a dose of 1-2 mg/kg clomipramine twice daily to give a total daily dose of 2-4 mg/kg according to the following table:

	Dosage per administration		
Body weight	Clomicalm 5 mg	Clomicalm 20 mg	Clomicalm 80 mg
1.25 - 2.5 kg	½ tablet		
> 2.5 - 5 kg	1 tablet		
> 5 - 10 kg		½ tablet	
> 10 - 20 kg		1 tablet	
> 20 - 40 kg			½ tablet
> 40 - 80 kg			1 tablet

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

The veterinary medicinal product may be given orally with or without food.

In clinical trials, a treatment time of 2-3 months with the veterinary medicinal product in combination with behavioural modification techniques was sufficient to control the symptoms of separation-related disorders. Some cases may require longer treatment. In cases showing no improvement after 2 months, treatment with the veterinary medicinal product should be ceased.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At overdose with 20 mg/kg of the veterinary medicinal product (5 times the maximum therapeutic dose), bradycardia and arrhythmias (atrioventricular node block and ventricular escape beats) were observed approximately 12 hours after dosing. Overdose with 40 mg/kg of the veterinary medicinal product (20 times the recommended dose) produced hunched posture, tremors, flushed abdomen and

decreased activity in dogs. Higher doses (500 mg/kg i.e. 250 times the recommended dose) produced emesis, defecation, drooped eyes, trembling and quietness. Still higher doses (725 mg/kg) produced, in addition, convulsions and death. Post-Approval Experience: in an overdose situation, mydriasis has been reported.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN06AA04.

4.2 Pharmacodynamics

Clomipramine has a broad-spectrum of action in blocking the neuronal reuptake of both serotonin (5-HT) and noradrenaline. It therefore possesses the properties of a serotonin re-uptake inhibitor and a tricyclic antidepressant.

The active components *in vivo* are clomipramine and its major metabolite, desmethylclomipramine. Both clomipramine and desmethylclomipramine contribute to the effects of the veterinary medicinal product: clomipramine is a potent and selective 5-HT reuptake inhibitor while desmethylclomipramine is a potent and selective noradrenaline reuptake inhibitor. The principle mechanism of action of clomipramine is potentiation of the effects of 5-HT and noradrenaline in the brain by inhibiting their neuronal reuptake. In addition, clomipramine has anticholinergic effects by antagonism of cholinergic muscarinic receptors.

4.3 Pharmacokinetics

Clomipramine is well absorbed (> 80 %) from the gastrointestinal tract in dogs when administered orally but the systemic bioavailability for clomipramine and desmethylclomipramine is 22-26 % due to extensive first pass metabolism by the liver. Peak plasma levels of clomipramine and desmethylclomipramine are rapidly reached (approx. 1.5-2.5 hours). The maximal plasma concentrations (C_{max}) after oral administration of single doses of 2 mg/kg clomipramine hydrochloride were: 240 nmol/l for clomipramine and 48 nmol/l for desmethylclomipramine. Repeated administration of the veterinary medicinal product causes moderate increases in plasma concentrations, accumulation ratios after oral administration twice daily were 1.2 for clomipramine and 1.6 for desmethylclomipramine, with steady state being reached within 3 days. At steady state, the ratio of plasma clomipramine to desmethylclomipramine concentrations is approximately 3:1. Administration of the veterinary medicinal product with food causes moderately higher plasma AUC values for clomipramine (25 %) and desmethylclomipramine (8 %) as compared with administration to fasted dogs. Clomipramine is extensively bound to plasma proteins (> 97 %) in dogs. Clomipramine and its metabolites are rapidly distributed in the body in mice, rabbits, and rats with high concentrations being achieved in organs and tissues (including the lungs, heart and brain) and low concentrations remaining in the blood. In dogs, the volume of distribution (VDss) is 3.8 l/kg. The major route of biotransformation of clomipramine is demethylation to desmethylclomipramine. Additional polar metabolites also exist. The elimination $t_{1/2}$ after intravenous administration of clomipramine hydrochloride in dogs was 6.4 hours for clomipramine and 3.6 hours for desmethylclomipramine. The principle route of excretion in dogs is via the bile (> 80 %) with the remainder via the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

5.3 Special precautions for storage

Store in the original container.

5.4 Nature and composition of immediate packaging

One HDPE bottle with child-resistant closure and sealing disk, containing 30 tablets and one silica gel desiccant sachet, packed within a cardboard box.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/98/007/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 1 April 1998

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clomicalm 5 mg tablets
Clomicalm 20 mg tablets
Clomicalm 80 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

5 mg clomipramine hydrochloride (equivalent to 4.5 mg clomipramine)
20 mg clomipramine hydrochloride (equivalent to 17.9 mg clomipramine)
80 mg clomipramine hydrochloride (equivalent to 71.7 mg clomipramine)

3. PACKAGE SIZE

30 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

EU/2/98/007/001 (5 mg, 30 tablets)
EU/2/98/007/002 (20 mg, 30 tablets)
EU/2/98/007/003 (80 mg, 30 tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clomicalm

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

5 mg 1.25 - 5 kg
20 mg 5 - 20 kg
80 mg 20 - 80 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clomicalm 5 mg tablets for dogs
Clomicalm 20 mg tablets for dogs
Clomicalm 80 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Clomipramine hydrochloride	5 mg (equivalent to 4.5 mg clomipramine)
Clomipramine hydrochloride	20 mg (equivalent to 17.9 mg clomipramine)
Clomipramine hydrochloride	80 mg (equivalent to 71.7 mg clomipramine)

5 mg tablet: Brownish-grey, oval-oblong, divisible. Scored on both sides.

20 mg tablet: Brownish-grey, oval-oblong, divisible. One side bears the imprint 'C/G', the other 'G/N' and scored on both sides.

80 mg tablet: Brownish-grey, oval-oblong, divisible. One side bears the imprint 'I/I', the other no imprint and scored on both sides.

3. Target species

Dogs.

4. Indications for use

As an aid in the treatment of separation-related disorders in dogs manifested by destruction and inappropriate elimination (defaecation and urination) and only in combination with behavioural modification techniques.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, to any of the excipients or to related tricyclic antidepressants.
Do not use in male breeding dogs.

6. Special warnings

Special warnings:

The efficacy and safety of the veterinary medicinal product have not been established in dogs weighing less than 1.25 kg or under six months of age.

Special precautions for safe use in the target species:

It is recommended that the veterinary medicinal product be administered to dogs with cardiovascular dysfunction or epilepsy with caution and only after an assessment of the benefit-risk ratio. Because of its potential anticholinergic properties, the veterinary medicinal product should also be used with care in dogs with narrow-angle glaucoma, reduced gastrointestinal motility or urinary retention. The veterinary medicinal product should be used under veterinary supervision.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In children, accidental ingestion should be regarded as serious. There is no specific antidote. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Overdose in human beings causes anticholinergic effects although central nervous and cardiovascular systems may also be affected. People with known hypersensitivity to clomipramine should administer the veterinary medicinal product with caution.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Laboratory studies in mice and rats have shown evidence of embryotoxic effects.

Interaction with other medicinal products and other forms of interaction:

Recommendations on the interaction between the veterinary medicinal product and other medicaments are derived from studies in species other than dogs. The veterinary medicinal product may increase the effects of the anti-arrhythmic medicinal products quinidine, anticholinergic agents (e.g. atropine), other central nervous system (CNS) medicinal products (e.g. barbiturates, benzodiazepines, general anaesthetics, neuroleptics), sympathomimetics (e.g. adrenaline) and coumarin derivatives. The administration of the veterinary medicinal product is not recommended in combination with, or within 2 weeks of therapy with monoamine oxidase inhibitors. Simultaneous administration with cimetidine may lead to increased plasma levels of clomipramine. Plasma levels of certain anti-epileptic medicinal products, such as phenytoin and carbamazepine, may be increased by co-administration with the veterinary medicinal product.

Overdose:

At overdose with 20 mg/kg of the veterinary medicinal product (5 times the maximum therapeutic dose), bradycardia and arrhythmias (atrioventricular node block and ventricular escape beats) were observed approximately 12 hours after dosing. Overdose with 40 mg/kg of the veterinary medicinal product (20 times the recommended dose) produced hunched posture, tremors, flushed abdomen and decreased activity in dogs. Higher doses (500 mg/kg i.e. 250 times the recommended dose) produced emesis, defecation, drooped eyes, trembling and quietness. Still higher doses (725 mg/kg) produced, in addition, convulsions and death. Post-Approval Experience: in an overdose situation, mydriasis (enlarged pupils) has been reported.

7. Adverse events

Dogs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):

Vomiting[1,2], Diarrhoea Appetite disorder[2], Lethargy[2] Elevated liver enzymes[2] Convulsion, Mydriasis (enlarged pupils)[4] Agression
Undetermined frequency (cannot be estimated from the available data):
Hepato-biliary disorder[3]

[1] May be reduced by co-administration of the veterinary medicinal product with a small quantity of food.
[2] Reversible when the veterinary medicinal product is discontinued.
[3] Especially with pre-existing conditions, and concurrent administrations of medicinal products metabolised via the hepatic system.
[4] Can also be observed following overdose.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

The veterinary medicinal product should be administered orally at a dose of 1-2 mg/kg clomipramine twice daily to give a total daily dose of 2-4 mg/kg according to the following table:

Body weight	Clomicalm 5 mg	Clomicalm 20 mg	Clomicalm 80 mg
1.25 - 2.5 kg > 2.5 - 5 kg	½ tablet 1 tablet	--- ---	--- ---
> 5 - 10 kg > 10 - 20 kg	--- ---	½ tablet 1 tablet	--- ---
> 20 - 40 kg > 40 - 80 kg	--- ---	--- ---	½ tablet 1 tablet

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

The veterinary medicinal product may be given orally with or without food.

9. Advice on correct administration

In clinical trials, a treatment time of 2-3 months with the veterinary medicinal product in combination with behavioural modification techniques was sufficient to control the symptoms of separation-related disorders. Some cases may require longer treatment. In cases showing no improvement after 2 months, treatment with the veterinary medicinal product should be ceased.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/98/007/001-003

Cardboard box with 1 bottle containing 30 tablets.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representatives and contact details to report suspected adverse reactions:

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.