

**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 of Clomicalm 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:**

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Tablets.

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.

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Dog

### **4.2 Indications for use, specifying the 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.

### **4.3 Contraindications**

Do not use in case of known hypersensitivity to clomipramine and related tricyclic antidepressants.  
Do not use in male breeding dogs.

### **4.4 Special warnings for each target species**

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

### **4.5 Special precautions for use**

Special precautions for use in animals It is recommended that Clomicalm 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, Clomicalm should also be used with care in dogs with narrow angle glaucoma, reduced gastrointestinal motility or urinary retention. Clomicalm 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 product 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 product with caution.

#### **4.6 Adverse reactions (frequency and seriousness)**

Clomicalm may very rarely cause vomiting, changes in appetite, lethargy or an elevation in liver enzymes, which is reversible when the product is discontinued. Hepato-biliary disease has been reported, especially with pre-existing conditions, and concurrent administrations of drugs metabolized via the hepatic system. Vomiting may be reduced by co-administration of Clomicalm with a small quantity of food.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

#### **4.7 Use during pregnancy, lactation or lay**

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

Pregnancy:

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

#### **4.8 Interaction with other medicinal products and other forms of interaction**

Recommendations on the interaction between Clomicalm and other medicaments are derived from studies in species other than dogs. Clomicalm may potentiate the effects of the anti-arrhythmic drug quinidine, anticholinergic agents (e.g. atropine), other CNS active drugs (e.g. barbiturates, benzodiazepines, general anaesthetics, neuroleptics), sympathomimetics (e.g. adrenaline) and coumarin derivatives. The administration of Clomicalm 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 drugs, such as phenytoin and carbamazepine, may be increased by co-administration with Clomicalm.

#### **4.9 Amounts to be administered and administration route**

Clomicalm 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

Clomicalm may be given with or without food. In clinical trials, a treatment time of 2-3 months with Clomicalm 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 Clomicalm should be ceased.

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

At overdose with 20 mg/kg Clomicalm (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 (20 times the recommended dose) of Clomicalm 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.

#### 4.11 Withdrawal period(s)

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-selective monoamine re-uptake inhibitors,  
ATCvet code: QN06AA04.

#### 5.1 Pharmacodynamic properties

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, desmethyldomipramine. Both clomipramine and desmethyldomipramine contribute to the effects of Clomicalm: clomipramine is a potent and selective 5-HT reuptake inhibitor while desmethyldomipramine 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.

#### 5.2 Pharmacokinetic particulars

Clomipramine is well absorbed (>80%) from the gastrointestinal tract in dogs when administered orally but the systemic bioavailability for clomipramine and desmethyldomipramine is 22-26% due to extensive first pass metabolism by the liver. Peak plasma levels of clomipramine and desmethyldomipramine 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 desmethyldomipramine. Repeated administration of Clomicalm 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 Clomicalm 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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lactose monohydrate  
Microcrystalline cellulose  
Artificial meat flavour  
Crospovidone  
Povidone  
Colloidal anhydrous silica  
Magnesium stearate

### **6.2 Major Incompatibilities**

None known.

### **6.3 Shelf life**

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

### **6.4. Special precautions for storage**

Store in the original container.

### **6.5 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.

### **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 product should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

VIRBAC  
1ère avenue – 2065 m – LID  
06516 Carros  
France

**8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/98/007/001-003

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation 1 April 1998

Date of last renewal: 10 April 2008

**10 DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/> .

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

## **ANNEX II**

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturer responsible for batch release

VIRBAC  
1ère avenue – 2065 m – LID  
06516 Carros  
France

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Not applicable.

**· CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable



**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 for dogs  
Clomicalm 20 mg tablets for dogs  
Clomicalm 80 mg tablets for dogs

Clomipramine hydrochloride

**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. PHARMACEUTICAL FORM**

Tablet

**4. PACKAGE SIZE**

30 tablets

**5. TARGET SPECIES**

Dog

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use.

Clomicalm is administered twice daily at a dose of 1-2 mg/kg clomipramine to give a total daily dose of 2 - 4 mg/kg according to the following table:

Body weight	Clomicalm 5 mg
1.25-2.5 kg	½ tablet
>2.5-5 kg	1 tablet

Body weight	Clomicalm 20 mg
> 5-10 kg	½ tablet
>10-20 kg	1 tablet

  

Body weight	Clomicalm 80 mg
>20-40 kg	½ tablet
>40-80 kg	1 tablet

Read the package leaflet before use.

#### **8. WITHDRAWAL PERIOD(S)**

#### **9. SPECIAL WARNING(S), IF NECESSARY**

To be used under veterinary supervision. Read the package leaflet before use.

#### **10. EXPIRY DATE**

EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

Store in the original container.

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

Disposal: read package leaflet

#### **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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children. Accidental ingestion should be regarded as serious.

#### **15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC  
1ère avenue – 2065 m – LID  
06516 Carros

France

<b>16.    MARKETING AUTHORISATION NUMBER(S)</b>
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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)

<b>17.    MANUFACTURER'S BATCH NUMBER</b>
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Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**BOTTLE**

**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

Clomipramine hydrochloride

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

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. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

30 tablets

**4. ROUTE(S) OF ADMINISTRATION**

For oral use.

1-2 mg clomipramine/kg bw twice daily.

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

## **B. PACKAGE LEAFLET**

## **PACKAGE LEAFLET:**

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

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

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC  
1ère avenue – 2065 m – LID  
06516 Carros  
France

### **2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

Clomipramine hydrochloride

### **3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

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)

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.

### **4. INDICATION(S)**

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

### **5. CONTRAINDICATIONS**

Do not use in case of known hypersensitivity to clomipramine and related tricyclic antidepressants. Do not use in male breeding dogs.

### **6. ADVERSE REACTIONS**



Clomicalm may very rarely cause vomiting, changes in appetite, lethargy or an elevation in liver enzymes, which is reversible when the product is discontinued. Hepato-biliary disease has been reported, especially with pre-existing conditions, and concurrent administrations of drugs metabolized via the hepatic system. Vomiting may be reduced by co-administration with a small quantity of food.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated )
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated )
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dog

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

Clomicalm is administered twice daily at a dose of 1-2 mg/kg clomipramine 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	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

Clomicalm may be given orally with or without food.

## **9. ADVICE ON CORRECT ADMINISTRATION**

In clinical trials, a treatment time of 2-3 months with Clomicalm 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 Clomicalm should be ceased.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable

## **11. SPECIAL STORAGE PRECAUTIONS**

Store in the original container. Keep out of sight and reach of children as accidental ingestion should be regarded as serious.

Do not use after the expiry date which is stated on the label after EXP.

## **12. SPECIAL WARNING(S)**

Special warnings for each target species It is recommended that Clomicalm 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, Clomicalm should also be used with care in dogs with narrow angle glaucoma, reduced gastrointestinal motility or urinary retention. Clomicalm should be used under veterinary supervision. The efficacy and safety of Clomicalm has not been established in dogs weighing less than 1.25 kg or under six months of age.

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 product 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 product with caution.

**Pregnancy and lactation:** The safety of the veterinary medicinal product has not been established in female dogs during pregnancy and lactation. Laboratory animal 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 Clomicalm and other medicaments are derived from studies in species other than dogs. Clomicalm may increase the effects of the anti-arrhythmic drug quinidine, anticholinergic agents (e.g. atropine), other CNS active drugs (e.g. barbiturates, benzodiazepines, general anaesthetics, neuroleptics), sympathomimetics (e.g. adrenaline) and coumarine derivatives. The administration of Clomicalm 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 drugs, such as phenytoin and carbamazepine, may be increased by coadministration with Clomicalm.

**Overdose (symptoms, emergency procedures, antidotes):** At overdose with 20 mg/kg Clomicalm (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 (20 times the recommended dose) of Clomicalm 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.

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

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

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>

## **15. OTHER INFORMATION**

For animal treatment only.

Pack size: 30 tablets

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

**België/Belgique/Belgien**

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**Česká republika**

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**Ελλάδα**

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VIRBAC Sp. z o.o.  
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**România**

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**Slovenija**

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**Slovenská republika**

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**Suomi/Finland**

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**Sverige**

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**United Kingdom (Northern Ireland)**

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FR-06516 Carros  
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