

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

| |
|--|
| 16. MARKETING AUTHORISATION NUMBER(S) |
|--|

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)

| |
|--|
| 17. MANUFACTURER'S BATCH NUMBER |
|--|

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.

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Slovenská republika

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United Kingdom (Northern Ireland)

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