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)

Vm 05653/5027 (5 mg, 30 tablets)
Vm 05653/5028 (20 mg, 30 tablets)
Vm 05653/5029 (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 are 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.
Clomicalm may very rarely cause diarrhoea, aggression, convulsion or mydriasis as well. Mydriasis can also be observed following overdose.

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 >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

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 form such veterinary medicinal products should be disposed of in accordance with local requirements.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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.

Local representative:
Virbac Ltd,
Suffolk, IP 30 9UP-UK
Tel: +44(0)-1359 243243

Gavin Hall

Approved: 22 January 2025