ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeguard Duo 12.5 mg / 125 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Milbemycin oxime 12.5 mg/tablet
Praziquantel 125 mg/tablet

3. PACKAGE SIZE

2 tablets
4 tablets
10 tablets
24 tablets
48 tablets
100 tablets

4. TARGET SPECIES

Dogs weighing at least 2.5 kg

5. INDICATIONS

For pack sizes not subject to veterinary prescription:
For the treatment of mixed infections by adult cestodes and nematodes and the prevention of heartworm disease in dogs if concomitant treatment against cestodes is indicated.
Recommended for dogs between 2.5 and 50 kg body weight according to the dosing table below:

Body Weight (kg)	12.5 mg/125 mg tablets
2.5 - 5	1/2 tablet
>5-25	1 tablet
>25-50	2 tablets

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life for halved tablet after first opening the blister: 6 months

9. SPECIAL STORAGE PRECAUTIONS

Any unused tablet parts should be returned to the opened blister, inserted back into the outer packaging and used at the next administration or securely discarded.
Protect from light.

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

Ceva Sante Animale

14. MARKETING AUTHORISATION NUMBERS

Vm 14966/3009

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeguard Duo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

12.5 mg milbemycin oxime and 125 mg praziquantel per tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Milbeguard Duo 12.5 mg / 125 mg chewable tablets for dogs

2. Composition

Each tablet contains:
Active substances:

Milbemycin oxime	12.5 mg
Praziquantel	125 mg

Round tablet, beige to light brown, scored on one side. The tablet can be divided into two equal parts.

3. Target species

Dogs weighing at least 2.5 kg.

4. Indications for use

In dogs: treatment of mixed infections by adult cestodes and nematodes of the following species:

- Cestodes:
Dipylidium caninum
Taenia spp.
Echinococcus spp.
Mesocestoides spp.

- Nematodes:
Ancylostoma caninum
Toxocara canis
Toxascaris leonina
Trichuris vulpis
Crenosoma vulpis (Reduction of the level of infection)
Angiostrongylus vasorum (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and prevention disease schedules under section “Dosage for each species, routes and method of administration”)

Thelazia callipaeda (see specific treatment schedule under section “Dosage for each species, routes and method of administration”)

The product can also be used in the prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

5. Contraindications

Do not use in dogs weighing less than 2.5 kg
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
See also section “Special precautions for safe use in the target species".

6. Special warnings

Special warnings:
It is recommended to treat all the animals living in the same household concomitantly. When infection with the cestode *D. caninum* has been confirmed, concomitant treatment against intermediate hosts, such as fleas and lice, should be discussed with a veterinarian to prevent re-infection.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
In third countries (USA), resistance of *Dipylidium caninum* to praziquantel as well as cases of multi-drug resistance of *Ancylostoma caninum* to milbemycin oxime, and resistance of *Dirofilaria immitis* to macrocyclic lactones have already been reported.
It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.
In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum product should be used.
The use of this product should take into account local information about susceptibility of the target parasites, where available.

Special precautions for safe use in the target species:

In heartworm risk-areas, or if it is known that a dog has been travelling to and from heartworm risk regions, before using the product, a veterinary consultation is advised to exclude the presence of any concurrent infestation of *Dirofilaria immitis*. In the case of a positive diagnosis, adulticidal therapy is indicated before administering the product.

Treatment of dogs with a high number of circulating microfilariae can sometimes lead to the appearance of hypersensitivity reactions, such as pale mucous membranes, vomiting, trembling, laboured breathing or excessive salivation. These reactions are associated with the release of proteins from dead or dying microfilariae and are not a direct toxic effect of the product. The use in dogs suffering from microfilaremia is thus not recommended.

No studies have been performed with severely debilitated dogs or individuals with seriously compromised kidney or liver function. The product is not recommended for such animals or only according to a benefit/risk assessment by the responsible veterinarian.

Studies with milbemycin oxime indicate that the margin of safety in MDR1 mutant (-/-)dogs of Collie or related breeds is lower compared to the non-mutant population. In these dogs, the recommended dose should be strictly observed. The tolerance of the product in young puppies from these breeds has not been investigated. Clinical signs in Collies are similar to those seen in the general dog population when overdosed (see section “Overdose”).

In dogs less than 4 weeks old, tape worm infection is unusual. Treatment of animals less than 4 weeks old with a combination product may therefore not be necessary.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be harmful when ingested, particularly for children. To avoid accidental ingestion, the product should be stored out of sight and reach of children. Any unused tablet parts should be returned to the opened blister, inserted back into the outer packaging and used at the next administration or securely discarded (see section “Special precautions for disposal”).
In case of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
The product may cause a weak skin sensitisation. Do not handle this product in case of known hypersensitivity to the active substances or to any of the excipients.
If symptoms such as skin rash persist, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The safety of the veterinary medicinal product has been established during pregnancy and lactation.
Can be used during pregnancy and lactation.

Fertility
Can be used in breeding dogs.

Interaction with other medicinal products and other forms of interaction:
The concurrent use of a tablet containing milbemycin oxime and praziquantel with selamectin is well tolerated. No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during the treatment with a tablet containing milbemycin oxime and praziquantel at the recommended dose. In the absence of further studies, caution should be taken in the case of concurrent use of a tablet containing milbemycin oxime and praziquantel and other

macrocyclic lactones. Also, no such studies have been performed with reproducing animals.

Overdose:
No other signs than those observed at the recommended dose have been observed (see section “Adverse events”).

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Not applicable.

Other Precautions:
Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (WOAH), specific guidelines on the treatment and follow up and on the safeguard of persons need to be obtained from the relevant competent authority (e.g., experts or institutes of parasitology).

7. Adverse events

Dogs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction, Systemic disorders (e.g. Lethargy, Anorexia), Neurological signs (e.g. Muscle tremor, Ataxia, Convulsion), Digestive tract disorders (e.g. Vomiting, Drooling, Diarrhoea)

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal 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 using the contact details at the end of this leaflet, or via your national reporting system.

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

Oral use.
Minimum recommended dose rate: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg are given once orally.
Animals should be weighed to ensure accurate dosing. Depending on the bodyweight of the dog, the practical dosing is as follows:

Body Weight (kg)	12.5 mg/125 mg chewable tablets
2.5 - 5	1/2 tablet
>5-25	1 tablet
>25-50	2 tablets

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, the veterinary medicinal product can replace the monovalent product for the prevention of heartworm disease.
For treatment of *Angiostrongylus vasorum* infections, milbemycin oxime should be given four times at weekly intervals. It is recommended, where concomitant treatment against cestodes is indicated, to treat once with the product and continue with the monovalent product containing milbemycin oxime alone, for the remaining three weekly treatments.
In endemic areas administration of the product every four weeks will prevent angiostrongylosis by reducing immature adult (L5) and adult parasite burden, where concomitant treatment against cestodes is indicated.
For the treatment of *Thelazia callipaeda*, milbemycin oxime should be given in 2 treatments, seven days apart. Where concomitant treatment against cestodes is indicated, the product can replace the monovalent product containing milbemycin oxime alone.
Underdosing could result in ineffective use and may favour resistance development.
The need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

9. Advice on correct administration

The veterinary medicinal product should be administered with or after some food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Any unused tablet parts should be returned to the opened blister, inserted back into the outer packaging and used at the next administration or securely discarded (see section Special precautions for disposal).

Protect from light.

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

Shelf life for halved tablet after first opening the blister: 6 months.

12. Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as this may be dangerous for fish and other aquatic organisms.
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

Cardboard box with 1 blister of 2 tablets (2 tablets).
Cardboard box with 2 blisters of 2 tablets (4 tablets).
Cardboard box with 5 blisters of 2 tablets (10 tablets).
Cardboard box with 12 blisters of 2 tablets (24 tablets).
Cardboard box with 24 blisters of 2 tablets (48 tablets).
Cardboard box with 50 blisters of 2 tablets (100 tablets).
Not all pack sizes may be marketed.

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15. 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.

16. Contact details

Marketing authorisation holder:

Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

Tel: +800 35 22 11 51
Email: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, Boulevard de la Communication, Zone Autoroutière, 53950 Louverné, France

17. Other information

Gavin Hall
Approved: 01 October 2025