PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeguard Duo 12.5 mg / 125 mg chewable tablets

2. STATEMENT OF ACTIVE AND OTHER 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 (dogs weighing at least 2.5 kg)

5. INDICATION(S)

For pack sizes not subject to veterinary prescription:
Treatment of mixed infections by adult cestodes and nematodes. The product can also be used in the prevention of heartworm disease if concomitant treatment against cestodes is indicated.
See section “Indications” on the package leaflet for further details.

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

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

Vm 15052/5038

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeguard Duo 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

12.5 mg milbemycin oxime and 125 mg praziquantel per tablet.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE 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

Chewable tablet.
Flavoured round tablet, beige to light brown, scored on one side. The tablet can be divided into equal halves.

3. TARGET SPECIES

Dogs (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 WARNING(S)

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 the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum product should be used when available.
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 certain dogs of Collie or related breeds is less than in other breeds. 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 part of tablet should be stored in the opened blister, inside the outer packaging and always be used at the next administration.
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 sensitization. Do not handle this product in case of known hypersensitivity to the active substances or to any of the excipients.
Wash hands after use.

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

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

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

7. ADVERSE EVENTS

Dogs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction, Lethargy, Anorexia, Muscle tremor, Ataxia, Convulsion, Emesis, Drooling, Diarrhoea

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 using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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)	12.5/125 tablet
2.5 - 5	1/2
>5-25	1
>25-50	2

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, the 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

Tablets are palatable. They should be administered with or after some food.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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
Halved tablets should be stored in the original blister and be used for the next administration.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Not all pack sizes may be subject to prescription.
(Pack sizes to be completed nationally).

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.

Vm 15052/5038

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

{dd/mm/yyyy}

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
(Name and address to be completed nationally)
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

(To be completed nationally)

Approved 02 November 2023