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

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbeguard Duo 16 mg / 40 mg film-coated tablets

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Milbemycin oxime 16 mg/tablet
Praziquantel 40 mg/tablet

## 3. PACKAGE SIZE

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

## 4. TARGET SPECIES

Cats (weighing at least 2 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 15052/5039

## 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)

16 mg milbemycin oxime and 40 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 16 mg / 40 mg film-coated tablets for cats

## 2. COMPOSITION

Each tablet contains:
**Active substances:**

| | |
|---|---|
| Milbemycin oxime | 16 mg |
| Praziquantel | 40 mg |

Film-coated tablet.
Flavoured oblong tablet, red to reddish brown, scored on one side. The tablet can be divided into equal halves.

## 3. TARGET SPECIES

Cats (weighing at least 2 kg)

## 4. INDICATIONS FOR USE

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

- Cestodes:
  *Dipylidium caninum*
  *Taenia* spp.
  *Echinococcus multilocularis*

- Nematodes:
  *Ancylostoma tubaeforme*
  *Toxocara cati*

Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

## 5. CONTRAINDICATIONS

Do not use in cats weighing less than 2 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## 6. SPECIAL WARNING(S)

Special warnings:
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.
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.
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:
Ensure cats and kittens weighing between 0.5 kg and ≤2 kg receive the correct dose of the 4/10 mg strength tablet.

No studies have been performed with severely debilitated cats 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.
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 the event 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.
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.

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 treatment with the product at the recommended dose.
Although not recommended, the concomitant use of the product with a spot on containing moxidectin and imidacloprid at recommended dose rates following a single application was well tolerated in one laboratory study in 10 kittens.
The safety and efficacy of the concurrent use have not been investigated in field studies. In the absence of further studies, caution should be taken in the case of concurrent use of the product with any other macrocyclic lactone. Also, no such studies have been performed with reproducing animals.

Overdose:
In case of overdose, in addition to signs observed at the recommended dose (see section" Adverse events"), drooling was observed. This sign will usually disappear spontaneously within a day.

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

Cats:

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

[1]: especially in young cats

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.
Animals should be weighed to ensure accurate dosing. Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given orally as a single dose.
Depending on the bodyweight of the cat, the practical dosing is as follows:

| Body weight (kg) | 16/40 tablets |
|---|---|
| 2-4 | 1/2 |
| >4-8 | 1 |
| >8-12 | 1+1/2 |

The product can be inserted into a program for prevention of heartworm disease if at the same time treatment against tapeworms is indicated. The product has a duration of heartworm prevention of one month. For regular prevention of heartworm disease, the use of a monosubstance is preferred.
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 tablets 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.

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## 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

Approved 26 October 2023