A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amcofen 2.5 mg/25 mg chewable tablets for small dogs and puppies weighing at least 0.5 kg
Milbemycin oxime/praziquantel

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet: milbemycin oxime 2.5 mg and praziquantel 25.0 mg.

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

2 tablets
4 tablets
48 tablets

5. TARGET SPECIES

Dogs (small dogs and puppies)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life for halved tablets after first opening the immediate packaging: 6 months.

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.
Halved tablets should be stored below 25°C in the original blister and be used for the next administration.
Keep the blister in the outer carton.

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.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto, Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4168

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amcofen 2.5 mg/25 mg chewable tablets for small dogs and puppies
Milbemycin oxime/praziquantel
Milbemycinum oximum/praziquantelum (for multilingual packaging)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Amcofen 2.5 mg/25 mg chewable tablets for small dogs and puppies weighing at least 0.5 kg
Amcofen 12.5 mg/125 mg chewable tablets for dogs weighing at least 5 kg

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

Manufacturer responsible for batch release:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amcofen 2.5 mg/25 mg chewable tablets for small dogs and puppies weighing at least 0.5 kg
Amcofen 12.5 mg/125 mg chewable tablets for dogs weighing at least 5 kg
Milbemycin oxime/praziquantel

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each chewable tablet contains:

	Chewable tablets for small dogs and puppies	**Chewable tablets for dogs**
Active substances:		
Milbemycin oxime	2.5 mg	12.5 mg
Praziquantel	25 mg	125 mg

Tablets for small dogs and puppies: Yellowish-white with brown spots, oval, biconvex tablets scored on one side.
The tablets can be divided into equal halves.

Tablets for dogs: Yellowish-white with brown spots, round, slightly biconvex tablets.

4. INDICATION(S)

Treatment of mixed infections by adult tapeworms and roundworms of the following species:

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

- Roundworms:
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 disease prevention schedules under section “Dosage for each species, route(s) and method of administration”).

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

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

5. CONTRAINDICATIONS

Do not use tablets for small dogs and puppies in animals of less than 2 weeks of age and/or weighing less than 0.5 kg.
Do not use tablets for dogs in animals weighing less than 5 kg.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.
See also section “Special warning(s)”.

6. ADVERSE REACTIONS

On very rare occasions, hypersensitivity reaction, systemic signs (such as lethargy), neurological signs (such as muscle tremors and ataxia/uncoordinated movements) and/or gastrointestinal signs (such as vomiting, diarrhoea, loss of appetite and drooling) have been observed in dogs after administration of the combination of milbemycin oxime and praziquantel.

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.

Alternatively you can report via your national reporting system:
https://www.gov.uk/report-veterinary-medicine-problem.

7. TARGET SPECIES

Small dogs and puppies (weighing at least 0.5 kg).
Dogs (weighing at least 5 kg).

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: 0.5 mg of milbemycin oxime and 5 mg of praziquantel per kg are given once orally.

Depending on the bodyweight of the dog, the practical dosing is as follows:

Body weight	Chewable tablets for small dogs and puppies	Chewable tablets for dogs
0.5 – 1 kg	1/2 tablet	
more than 1 – 5 kg	1 tablet	
more than 5 – 10 kg	2 tablets	
5 – 25 kg		1 tablet
more than 25 – 50 kg		2 tablets
more than 50 – 75 kg		3 tablets

In cases when heartworm disease prevention is used and at the same time treatment against tapeworm is required, the product can replace the monosubstance 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 tapeworms 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 tapeworms is indicated.

For the treatment of *Thelazia callipaeda*, milbemycin oxime should be given in 2 treatments, seven days apart. Where concomitant treatment against tapeworms is indicated, the product can replace the monosubstance product containing milbemycin oxime alone.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered with or after some food.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package in order to protect from moisture. This veterinary medicinal product does not require any special temperature storage conditions.
Shelf life for halved tablets for small dogs and puppies after first opening the immediate packaging: 6 months.
Halved tablets should be stored below 25°C in the original blister and be used for the next administration.
Keep the blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton after {EXP}. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
It is recommended to treat all the animals in the same household concomitantly.
In order to develop an effective worm control programme local epidemiological information and the risk of exposure of the dog should be taken into account, and it is recommended to seek professional (e. g. veterinary) advice.
When *D. caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent re-infection.

Special precautions for use in animals:
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.
Treatment of dogs with a high number of circulating microfilariae (larvae) 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 (larvae) and are not a direct toxic effect of the product. The use in dogs suffering from microfilaremia (larvae in the blood) is thus not recommended.
In heartworm risk-areas, or in the case 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 pre-existing infestation of *Dirofilaria immitis*. If infestation with *Dirofilaria immitis* is diagnosed, the dog should be treated against adult parasites, adulticidal therapy is indicated before administering the product.
No studies have been performed with severely debilitated dogs or individuals with seriously impaired kidney or liver function. The product is not recommended for such animals or only according to a benefit/risk assessment by the responsible veterinarian.

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.
As the tablets are flavoured, they should be stored in a safe place out of the reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental ingestion of a tablet by a child may be harmful. In order to prevent children from accessing the product, tablets should be administered and stored out of sight and reach of children.
Part tablets should be returned to the open blister pocket and inserted into the outer carton.
In the event of accidental ingestion of one or more tablets, seek medical advice immediately and show the package leaflet or the label to the doctor.Wash hands after use.
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 (e. g. experts or institutes of parasitology).

Pregnancy and lactation:
The product may be used in breeding dogs including pregnant and lactating bitches.

Interaction with other medicinal products and other forms of interaction:
No interactions were observed when the recommended dose of the macrocyclic lactone selamectin was administered during treatment with the combination of 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 the product and other macrocyclic lactones. Also, no such studies have been performed with reproducing animals.

Overdose (symptoms, emergency procedures, antidotes):
No other signs than those observed at the recommended dose have been observed (see “Adverse events”).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.
The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

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

Cardboard box with 1 blister of 2 tablets.
Cardboard box with 1 blister of 4 tablets.
Cardboard box with 12 blisters, each blister contains 4 tablets (total 48 tablets).
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved: 18 June 2024

Gavin Hall