

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substances:

Milbemycin oxime	16.0 mg
Praziquantel	40.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Core:	
Cellulose microcrystalline	
Croscarmellose sodium	
Magnesium stearate	
Povidone	
Silica hydrophobic colloidal	
Coat:	
Poultry liver flavour	
Hypromellose	
Cellulose microcrystalline	
Macrogol stearate	
Allura Red AC (E129)	0.1 mg
Titanium Dioxide (E171)	0.5 mg

Film-coated tablet.

Oval shaped, red to pink, tablets with a score on both sides.

The tablets can be divided into halves.

3. CLINICAL INFORMATION

3.1 Target species

Cats (weighing at least 2 kg).

3.2 Indications for use for each target species

For cats with, or at risk from mixed infections of cestodes, nematodes and/or heartworm. The veterinary medicinal product is only indicated when the use against cestodes and nematodes is required at the same time.

Cestodes:

Treatment of tapeworms:

Dipylidium caninum,

Taenia spp.,

Echinococcus multilocularis.

Gastrointestinal nematodes:

Treatment of:

Hookworm: *Ancylostoma tubaeforme*,
Roundworm: *Toxocara cati*.

Heartworm:

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

3.3 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.

3.4 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 veterinary medicinal 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 animal.

In the absence of risk of co-infection, a narrow spectrum veterinary medicinal product should be used.

The possibility that other animals in the same household can be a source of re-infection with nematodes and/or cestodes should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Resistance of *Dypilidium caninum* to praziquantel and, an imported case of resistance of *Dirofilaria immitis* to milbemycin oxime, a macrocyclic lactone, have been reported in Europe.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

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.

When *Dypilidium caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent re-infection.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Ensure cats and kittens weighing between 0.5 kg and ≤ 2 kg receive the appropriate tablet strength (4 mg milbemycin oxime / 10 mg praziquantel) and the appropriate dose. See also section 3.9 "Administration routes and dosage".

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

The product may be harmful in case of ingestion, especially by a child.
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.

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 doctor.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Echinococcosis represents a hazard for humans and is a notifiable disease to the World Organisation for Animal Health (WOAH). In case of echinococcosis, specific guidelines on the treatment and follow up and on the safeguard of persons have to be followed (e.g., experts or institutes of parasitology).

3.6 Adverse events

Cats:

<p>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</p>	<p>Hypersensitivity reaction Systemic disorders (e.g lethargy and anorexia) Neurological disorders (e.g. muscle tremor, ataxia) Digestive tract disorders (e.g. emesis and diarrhoea)</p>
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

The concurrent use of the veterinary medicinal 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 veterinary medicinal product at the recommended dose.

Although not recommended, the concomitant use of the veterinary medicinal 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 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 with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg of bodyweight are given once as a single dose.

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

The tablets can be divided into halves.

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

Bodyweight	Tablets
2 – 4 kg	1/2 tablet
>4 – 8 kg	1 tablet
>8 – 12 kg	1½ tablets

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

For infections with cestodes and nematodes, 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, in addition to signs observed at the recommended dose (see section 3.6 “Adverse events”), drooling was observed. This sign will usually disappear spontaneously within a day.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB51.

4.2 Pharmacodynamics

Milbemycin oxime belongs to the group of macrocyclic lactones, isolated from the fermentation broth of *Streptomyces hygroscopicus* var. *aureolacrimosus*. It is active against mites, against larval and adult stages of nematodes as well as against larvae of *Dirofilaria immitis*.

The activity of milbemycin is related to its action on invertebrate neurotransmission increasing the cell membrane permeability to chloride ions that results in the hyperpolarization of the neuromuscular membrane and flaccid paralysis and death of the parasite.

Avermectins and milbemycin have similar molecular targets - glutamate-gated chloride channels. These channels have multiple isoforms in nematodes which may have different susceptibilities to avermectins/milbemycin. Different mechanisms of avermectins and milbemycin resistance may be due to the multiplicity of glutamate-gated chloride channels subtypes.

Praziquantel is an acylated pyrazino-isoquinoline derivative. Praziquantel is active against cestodes and trematodes. It acts primarily by changing the calcium permeability of the parasite membranes inducing an imbalance in the membrane structures, leading to membrane depolarisation and almost instantaneous contraction of the musculature (tetany), rapid vacuolization of the syncytial tegument and subsequent tegumental disintegration (blebbing), resulting in easier expulsion from the gastrointestinal tract or death of the parasite. The resistance mechanism for praziquantel is still unknown.

4.3 Pharmacokinetics

In the cat, praziquantel reaches peak plasma concentrations within 0.5-7 hours after oral administration. The half-life of elimination is found between 2 and 7 h.

After oral administration in the cat, milbemycin oxime A4 reaches peak plasma concentrations within 2-24 hours. The half-life of elimination is found between 15h to 99h.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

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

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

5.4 Nature and composition of immediate packaging

Oriented polyamide/Aluminium/Polyvinyl chloride-Aluminium blister with 2 tablets/blister in a cardboard box.

Pack sizes:

1 box containing 24 blister (48 tablets).

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

The veterinary medicinal product should not enter water courses as milbemycin oxime and praziquantel 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

ALFAMED

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**BOX****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:

Milbemycin oxime	16.0 mg
Praziquantel	40.0 mg

3. PACKAGE SIZE

48 tablets

4. TARGET SPECIES

Cats (weighing at least 2 kg).



[optional]

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Oral use.

7. WITHDRAWAL PERIODS**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 6 months.

Once opened use by...

9. SPECIAL STORAGE PRECAUTIONS

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

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

ALFAMED

14. MARKETING AUTHORISATION NUMBERS

MA number :

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**BLISTER****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Milbemycin oxime / Praziquantel Alfamed

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

16 mg / 40 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PACKAGE LEAFLET**1. Name of the veterinary medicinal product**

Milbemycin oxime / Praziquantel Alfamed 4 mg/10 mg film-coated tablets for small cats and kittens
Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats

2. Composition**Milbemycin oxime / Praziquantel Alfamed 4 mg/10 mg film-coated tablets for small cats and kittens**

Each film-coated tablet contains (small cats and kittens):

Milbemycin oxime	4.0 mg
Praziquantel	10.0 mg

Excipients:

Yellow iron oxide (E172)	0.1 mg
Red iron oxide (E172)	0.1 mg
Black iron oxide (E172)	0.1 mg
Titanium Dioxide (E171)	0.01 mg

Film-coated tablet.

Oval shaped, dark brown, tablets with a score on both sides.

The tablets can be divided into halves.

Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats

Each film-coated tablet contains (cats):

Milbemycin oxime	16.0 mg
Praziquantel	40.0 mg

Excipients:

Allura Red AC (E129)	0.1 mg
Titanium Dioxide (E171)	0.5 mg

Film-coated tablet.

Oval shaped, red to pink, tablets with a score on both sides.

The tablets can be divided into halves.

3. Target species

Milbemycin oxime / Praziquantel Alfamed 4 mg/10 mg film-coated tablets for small cats and kittens
Cats (small cats and kittens weighing at least 0.5 kg).

Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats
Cats (weighing at least 2 kg)

4. Indications for use

For cats with, or at risk from mixed infections of cestodes, nematodes and/or heartworm. The veterinary medicinal product is only indicated when the use against cestodes and nematodes is required at the same time.

Cestodes:

Treatment of tapeworms:

Dipylidium caninum,

Taenia spp.,

Echinococcus multilocularis.

Gastrointestinal nematodes:

Treatment of:

Hookworm: *Ancylostoma tubaeforme*,

Roundworm: *Toxocara cati*.

Heartworm:

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

5. Contraindications

Milbemycin oxime / Praziquantel Alfamed 4 mg/10 mg film-coated tablets for small cats and kittens	Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats
Do not use in kittens of less than 6 weeks of age and/or weighing less than 0.5 kg.	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 warnings

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 veterinary medicinal 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 animal.

In the absence of risk of co-infection, a narrow spectrum veterinary medicinal product should be used.

The possibility that other animals in the same household can be a source of re-infection with nematodes and/or cestodes should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Resistance of *Dypilidium caninum* to praziquantel and, an imported case of resistance of *Dirofilaria immitis* to milbemycin oxime, a macrocyclic lactone, have been reported in Europe.

The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.

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.

When *Dipylidium caninum* infection is present, concomitant treatment against intermediate hosts, such as fleas and lice, should be considered to prevent re-infection. It is recommended to treat all the animals living in the same household concomitantly.

Special precautions for safe use in the target species:

Ensure cats and kittens weighing between 0.5 kg and ≤ 2 kg receive the appropriate tablet strength (4 mg milbemycin oxime / 10 mg praziquantel) and the appropriate dose. See also section 3.9 “Administration routes and dosage”.

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

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:

The product may be harmful in case of ingestion, especially by a child.

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 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 doctor.

Wash hands after use

Other precautions:

Echinococcosis represents a hazard for humans and is a notifiable disease to the World Organisation for Animal Health (WOAH). In case of echinococcosis, specific guidelines on the treatment and follow up and on the safeguard of persons have to be followed (e.g., experts or institutes of parasitology)

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Fertility:

Can be used in breeding animals.

Interaction with other medicinal products and other forms of interaction:

The concurrent use of the veterinary medicinal 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 veterinary medicinal product at the recommended dose.

Although not recommended, the concomitant use of the veterinary medicinal 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 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 with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals.

Overdose:

In case of overdose, in addition to signs observed at the recommended dose (see section 3.6 “Adverse events”), drooling was observed. This sign will usually disappear spontaneously within a day.

7. Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction Systemic disorders (e.g lethargy and anorexia) Neurological disorders (e.g. muscle tremor, ataxia) Digestive tract disorders (e.g. emesis and diarrhoea)
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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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

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

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg of bodyweight are given once as a single dose.

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

Bodyweight	Milbemycin oxime / Praziquantel Alfamed 4 mg/10 mg film-coated tablets for small cats and kittens	Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats
0.5 - 1 kg	1/2 tablet	
> 1 – 2 kg	1 tablet	
2 – 4 kg		1/2 tablet
>4 – 8 kg		1 tablet
>8 – 12 kg		1½ tablets

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

For infections with cestodes and nematodes, 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.

The tablets can be divided into halves.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions. Half tablets should be stored in the original blister and be used for the next administration.

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

Shelf life after first opening the immediate packaging (for half tablets): 6 months.

12. Special precautions for disposal

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

The veterinary medicinal product should not enter water courses as milbemycin oxime and praziquantel 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

MA n°

Oriented polyamide/Aluminium/Polyvinyl chloride-Aluminium blister with 2 tablets/blister in a cardboard box.

Pack sizes:

Milbemycin oxime / Praziquantel Alfamed 4 mg/10 mg film-coated tablets for small cats and kittens

1 box containing 12 blister (24 tablets).

Milbemycin oxime / Praziquantel Alfamed 16 mg/40 mg film-coated tablets for cats

1 box containing 24 blister (48 tablets).

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

ALFAMED

13ème Rue

06517 Carros

France

Manufacturer responsible for batch release:

VIRBAC - 1ere Avenue LID 2065 M - 06516 Carros – FRANCE

ALFAMED - 13ème Rue - 06510 Carros - France