1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbetab 4 mg/10 mg film-coated tablets for small cats and kittens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Milbemycin oxime 4.0 mg
Praziquantel 10.0 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:	
Lactose Monohydrate	
Croscarmellose Sodium	
Microcrystalline Cellulose	
Povidone K30	
Silica, colloidal anhydrous	
Magnesium Stearate	
Coat:	
Titanium Dioxide (E171)	0.486 mg
Hypromellose	
Macrogol 4000	
Grilled Meat flavour	

White to off-white oval shaped film-coated tablet with break lines on both sides .
The tablets can be divided into halves.

3. CLINICAL INFORMATION

3.1 Target species

Cats (≥ 0.5 - 2 kg).

3.2 Indications for use for each target species

For cats with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease is indicated 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 of less than 6 weeks of age and/or weighing less than 0.5 kg.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

The possibility that other animals in the same household can be a source of re-infection should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.
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 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 individual animal.
In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used when available.
The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.
Resistance of *Dipylidium caninum* to praziquantel and resistance of *Dirofilaria immitis* to macrocyclic lactones have 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.

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.
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:

People with known hypersensitivity to milbemycin oxime/praziquantel should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may be harmful when ingested, particularly for children.
Avoid accidental ingestion.
Unused tablet parts should be discarded. The product should be stored in a safe place.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
See section 5.5.

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).

3.6 Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders (such as Diarrhoea, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia and Muscle tremor) Systemic disorders (such as Lethargy)

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 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 veterinary medicinal product with any other macrocyclic lactone. Also, no such studies have been performed with breeding animals.

3.9 Administration routes and dosage

Oral use.
Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given as a single dose.
The veterinary medicinal product should be administered with or after some food. Doing so ensures optimum protection against heartworm disease.

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.

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

Weight	Tablets
0.5 - 1 kg:	½ tablet
> 1 – 2 kg:	1 tablet

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 product has a duration of heartworm prevention of one month. For regular prevention of heartworm disease, the use of a narrow spectrum product containing a single active substance is preferred.

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:

QP54A B51

4.2 Pharmacodynamics

Milbemycin oxime belongs to the group of macrocyclic lactones, isolated from the fermentation 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. Milbemycin oxime, like avermectins and other milbemycins, increases nematode and insect membrane permeability to chloride ions via glutamate-gated chloride ion channels (related to vertebrate $GABA_A$ and glycine receptors). This leads to hyperpolarisation of the neuromuscular membrane and flaccid paralysis and death of the parasite.

Praziquantel is an acylated pyrazino-isoquinoline derivative. Praziquantel is active against cestodes and trematodes. It modifies the permeability for calcium (influx of Ca^{2+}) in the membranes of the parasite 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.

4.3 Pharmacokinetics

In the cat, praziquantel reaches peak plasma concentrations within 3 hours after oral administration. The half life of elimination is around 5 hours.

After oral administration in the cat, milbemycin oxime reaches peak plasma concentrations within 3 hours. The half life of elimination is around 47 hours

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years
Unused tablet parts should be discarded.

5.3 Special precautions for storage

Keep the blister in the outer carton in order to protect from light

5.4 Nature and composition of immediate packaging

Blister packs made up of a laminate of OPA/ALU/PVC with a hard tempered aluminium foil in a cardboard box.

Pack sizes:
1 cardboard box containing 2 tablets. (1 blister strip of 2)
1 cardboard box containing 4 tablets. (1 blister strip of 4 or (2 blister strips of 2)
1 cardboard box containing 10 tablets. (1 blister strip of 10 or 5 blisters strips of 2)
1 cardboard box containing 20 tablets. (2 blister strips of 10 or 10 blisters strips of 2)
1 cardboard box containing 50 tablets. (5 blister strips of 10)
1 cardboard box containing 100 tablets. (10 blister strips of 10)
Multipacks of 10 individual packs of 2 tablets
Multipacks of 10 individual packs of 20 tablets
Multipacks of 10 individual packs of 50 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Chanelle Pharmaceuticals Manufacturing Ltd.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/173/002

8. DATE OF FIRST AUTHORISATION

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbetab 4 mg/10 mg film-coated tablets for small cats and kittens (AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, HR, HU, IE, IT, NL, PL, PT, RO, SE)

Milipraz 4 mg/10 mg film-coated tablets for cats (NO)

2. STATEMENT OF ACTIVE SUBSTANCES

Each film-coated tablet contains:
Milbemycin oxime 4.0 mg
Praziquantel 10.0 mg

3. PACKAGE SIZE

2 tablets
4 tablets
10 tablets
20 tablets
50 tablets
100 tablets
10 x 2 tablets
10 x 20 tablets
10 x 50 tablets

4. TARGET SPECIES

Cats (≥ 0.5 - 2 kg).

5. INDICATIONS

For products not subject to veterinary prescription:
Tablets for the treatment of mixed infections by hookworms, roundworms, and tapeworms, as well as for the prevention of heartworms.

Weight	Dosage
0.5 - 1 kg:	½ tablet
> 1 – 2 kg:	1 tablet

Single oral administration with or after some food.

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep blister in the outer carton to 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

Chanelle Pharmaceuticals Manufacturing Ltd.,

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Milbetab /Milipraz

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Milbemycin oxime	4.0 mg/ film-coated tablet
Praziquantel	10.0 mg/ film-coated tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Milbetab 4 mg/10 mg film-coated tablets for small cats and kittens (AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, HR, HU, IE, IT, NL, PL, PT, RO, SE)
Milipraz 4 mg/10 mg film-coated tablets for cats (NO)

Milbetab 16 mg/40 mg film-coated tablets for cats (AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, HR, HU, IE, IT, NL, PL, PT, RO, SE)
Milipraz 16 mg/40 mg film-coated tablets for cats (NO)

2. Composition

The veterinary medicinal products are available in 2 different sizes:

Name of Tablet	**Milbemycin oxime per tablet**	**Praziquantel per tablet**	**Excipients**
Milbetab/ Milipraz Film-coated tablets for small cats and kittens White to off-white oval shaped film-coated tablet with break lines on both sides. The tablets can be divided into halves.	4.0 mg	10.0 mg	Titanium dioxide 0.486 mg
Milbetab/Milipraz Film-coated tablets for cats Pink/orange oval shaped film-coated tablet with break lines on both sides. The tablets can be divided into halves	16.0 mg	40.0 mg	Titanium dioxide 0.519 mg Iron oxide Yellow (E172) 0.052 mg Iron oxide Red (E172) 0.036 mg

3. Target species

Cats (≥ 0.5 - 2 kg).

4. Indications for use

For cats with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease is indicated 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

Do not use the '**tablets for small cats and kittens'** in cats of less than 6 weeks of age and/or weighing less than 0.5 kg.
Do not use the '**tablets for cats'** in cats weighing less than 2 kg.
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

The possibility that other animals in the same household can be a source of re-infection should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.
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 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 individual animal.
In the absence of risk of co-infection with nematodes or cestodes, a narrow spectrum veterinary medicinal product should be used when available.
The use of this veterinary medicinal product should take into account local information about susceptibility of the target parasites, where available.
Resistance of *Dipylidium caninum* to praziquantel and resistance of *Dirofilaria immitis* to macrocyclic lactones have 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.

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 MBO/10 mg praziquantel) and the appropriate dose. See also section "dosage for each species, routes and method of administration".

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:
People with known hypersensitivity to milbemycin oxime/praziquantel should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may be harmful when ingested, particularly for children.
Avoid accidental ingestion.
Unused tablet parts should be discarded. The product should be stored in a safe place.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:
See section "Special precautions for disposal".

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).

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 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 veterinary medicinal product 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 7 "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):	Digestive tract disorders (such as Diarrhoea, Emesis) Hypersensitivity reaction Neurological disorders (such as Ataxia and Muscle tremor) Systemic disorders (such as Lethargy)

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, the local representative of 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.
Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.
Minimum recommended dose rate: 2 mg of milbemycin oxime and 5 mg of praziquantel per kg are given as a single dose.
The veterinary medicinal product should be administered with or after some food. Doing so ensures optimum protection against heartworm disease.

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.

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

Weight	Milbetab Tablets for small cats and kittens	Milbetab Tablets for cats
0.5 - 1 kg:	½ tablet (white to off white)	
> 1 – 2 kg:	1 tablet (white to off white)	
2 - 4 kg		½ tablet (pink/orange)
> 4 – 8 kg		1 tablet (pink/orange)
> 8 - 12 kg		1½ tablets (pink/orange)

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 product has a duration of heartworm prevention of one month. For regular prevention of heartworm disease, the use of a narrow spectrum product containing a single active substance is preferred.

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 blister in the outer carton to protect from light.
Keep out of sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.

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. [AT, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, NO, PL, PT, RO]
Veterinary medicinal product not subject to prescription. [BE, NL]
Veterinary medicinal product subject to prescription except for some pack sizes. [SE]

14. Marketing authorisation numbers and pack sizes

Pack sizes:
1 cardboard box containing 2 tablets. (1 blister strip of 2)
1 cardboard box containing 4 tablets. (1 blister strip of 4 or (2 blister strips of 2)
1 cardboard box containing 10 tablets. (1 blister strip of 10 or 5 blisters strips of 2)
1 cardboard box containing 20 tablets. (2 blister strips of 10 or 10 blisters strips of 2)
1 cardboard box containing 50 tablets. (5 blister strips of 10)
1 cardboard box containing 100 tablets. (10 blister strips of 10)
Multipacks of 10 individual packs of 2 tablets
Multipacks of 10 individual packs of 20 tablets
Multipacks of 10 individual packs of 50 tablets.

Not all pack sizes may be marketed.

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea, Co. Galway, H62 FH90
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.ie

17. Other information

Not applicable.