ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Interceptor Flavor 2.3 mg tablets for dogs (IT)
Interceptor Flavor 5.75 mg tablets for dogs (IT)
Interceptor Flavor 11.5 mg tablets for dogs (IT)
Interceptor Flavor 23 mg tablets for dogs (IT)

Interceptor vet. 2.3 mg tablets for dogs (DK, FI, NO, SE)
Interceptor vet. 5.75 mg tablets for dogs (DK, FI, NO, SE)
Interceptor vet. 11.5 mg tablets for dogs (DK, FI, NO, SE)
Interceptor vet. 23 mg tablets for dogs (DK, FI, NO, SE)

Interceptor F 11.5 mg tablets for dogs (FR)
Interceptor F 23 mg tablets for dogs (FR)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Milbemycin oxime

Product	Milbemycin oxime
2.3 mg tablet for very small dogs	2.3 mg
5.75 mg tablet for small dogs	5.75 mg
11.5 mg tablet for medium dogs	11.5 mg
23 mg tablet for large dogs	23 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Artificial beef flavour
Hydrogenated vegetable oil, Type 1
Croscarmellose sodium
Magnesium stearate
Silica, colloidal anhydrous / Colloidal silicon dioxide

Interceptor Flavor 2.3 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “RN” and no imprint on the other side.

Interceptor Flavor 5.75 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “GO” and no imprint on the other side.

Interceptor Flavor 11.5 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “FKF” and no imprint on the other side.

Interceptor Flavor 23 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “FRF and no imprint on the other side.

3. CLINICAL INFORMATION

3.1 Target species

Dog.

3.2 Indications for use for each target species

The product is indicated for

- the prevention of heartworm disease in dogs (*Dirofilaria immitis*),
- the treatment of intestinal worms such as whipworms (*Trichuris vulpis*), roundworms (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*) and
- the treatment of lungworms (*Crenosoma vulpis*) and the French heartworm (*Angiostrongylus vasorum*).

It is also indicated for

- the treatment of generalised demodicosis (*Demodex canis*),
- the treatment of mange induced by *Sarcoptes scabiei* var. *canis* and
- the treatment of nose mites (*Pneumonyssoides caninum*).

3.3 Contraindications

Dot not use in puppies under 2 weeks of age.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
See also section 3.5 "Special precautions for use".

3.4 Special warnings

As relapses in the case of generalised demodicosis are quite common, continued monitoring by a veterinarian is recommended after clinical signs have ceased.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
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/infestation based on its epidemiological features, for each individual animal.
Based on the diagnosis and recommendations by the responsible veterinarian, dogs and cats living in the same household may need to be treated with a suitable worm control product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The treatment of animals weighing less than 1 kg should be based on a benefit-risk evaluation.

This product contains milbemycin oxime, a macrocyclic lactone. Studies with milbemycin oxime indicated that the safety margin for Collies and related breeds is narrower than for other dog breeds. Therefore, the recommended dose should be complied with. The clinical signs in Collies and related breeds are similar to those observed in the general population of dogs when overdosed. In studies performed with milbemycin oxime, when given monthly at the recommended dose, no reaction of intolerance has been observed in more than 75 strains of dogs including Collies. The tolerance of milbemycin oxime in young puppies from these breeds has not been investigated.

No studies have been performed with debilitated dogs or dogs with seriously compromised kidney or liver function. Therefore, the product should be only used in debilitated animals after a benefit-risk evaluation by the responsible veterinarian.

During treatment of generalised demodicosis, especially with debilitated dogs, vomiting, diarrhoea, and somnolence can be observed. If the signs persist for longer than 48 hours, a reduction of the applied dose is recommended. If convulsion or ataxia is observed, treatment should be immediately discontinued until signs resolve and a veterinarian should be consulted for further treatment options.

The treatment of dogs with high numbers of circulating microfilariae can sometimes provoke a transient hypersensitivity reaction. The clinical signs e.g., pale mucous membrane, vomiting, tremors, laboured breathing and hypersalivation, can be attributed to the release of toxic proteins from dead or immobilized microfilariae, and are not due to any direct toxic effect of the veterinary product. Symptomatic treatment is recommended.

Therefore, before initiation of treatment with the product, especially in heartworm-risk areas or in case it is known that a dog has been travelling to and from heartworm risk regions, any concurrent infestation of *Dirofilaria immitis*, should be excluded. In the case when microfilariae are present and before application of the product, an adulticide therapy is recommended. Please refer to section 3.6 for hypersensitivity reactions.

The chewable 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:

Wash hands after handling the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dog

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting[1,2], Diarrhoea[1], Hypersalivation[2] Hypersensitivity reaction[3] Somnolence[1], Seizure[4], Tremors[2] Laboured breathing[2] Ataxia[4], Pale mucous membrane[2]

[1] During treatment of generalised demodicosis, especially in debilitated dogs. If the signs persist for longer than 48 hours, a reduction of the applied dose is recommended.
[2] Can be attributed to the release of toxic proteins from dead or immobilized microfilariae and are not due to any direct toxic effect of the veterinary product.
[3] The treatment of dogs with high numbers of circulating microfilariae can sometimes provoke a transient reaction. See also section 3.5.

[4] If these signs occur, treatment should be immediately discontinued until signs resolve and a veterinarian should be consulted for further treatment options.

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 the national competent authority via the national reporting system. See also the last section of 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.

3.8 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 milbemycin oxime at a dose rate of 0.5 mg/kg. 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.

3.9 Administration routes and dosage

Oral use.
The product is available in four strengths.
The tablets should be administered orally in a single dose and may be given with or after some food.
The recommended minimum dose is 0.5 mg milbemycin oxime per kg bodyweight, this corresponds to:

Body weight	Product	Strength (Milbemycin oxime / tablet)
up to 4.5 kg	One 2.3 mg tablet for very small dogs	2.3 mg
from 5 to 11 kg	One 5.75 mg tablet for small dogs	5.75 mg
from 12 to 22 kg	One 11.5 mg tablet for medium dogs	11.5 mg
from 23 to 45 kg	One 23 mg tablet for large dogs	23.0 mg

Prevention of heartworm disease (caused by *Dirofilaria immitis*)
Dogs in areas endemic for heartworm, or those, which have travelled to such areas, may be infected with adult heartworms. Prior to treatment with the product, the advice in section 3.5 'Special precautions for safe use in the target species' should be considered.
A single dose of 0.5–1.0 mg/kg is applied orally once per month, ideally always at the same day of the month.

For prevention of dirofilariosis, the treatment must be repeated every month. The first dose should be given within 30 days after the onset of and terminating 30 days after the end of the mosquito season. In case that an interval would exceed 30 days, immediately resume treatment at the prescribed dose. If the interruption would be greater than 60 days, a veterinarian should be consulted before resuming the treatment with the product.

The product, when substituting other products for the prevention of dirofilariosis, should be administered within 30 days after the last treatment.

In non-endemic areas there should be no risk of dogs having heartworms and they can be treated according to the local epidemiological situation.

Treatment of intestinal stages of whipworms (*Trichuris vulpis*), roundworms (*Toxocara canis*, *Toxacaris leonina*) and hookworms (*Ancylostoma caninum*)
The product is administered orally in a single dose of 0.5–1.0 mg/kg.

Treatment of lungworms (*Crenosoma vulpis*)
For *Crenosoma vulpis*, the product is administered orally in a single dose of 0.5–1.0 mg/kg.

Treatment of French heartworm (*Angiostrongulus vasorum*)
For *Angiostrongulus vasorum* infections, the product should be given orally in a single dose of 0.5–1.0 mg/kg four times at weekly intervals.

Treatment of generalised demodicosis (caused by *Demodex canis*)
The recommended dose is 0.5–1.0 mg/kg per day until two negative cutaneous scrapings are achieved within a month.
If it is justified by the clinical status and by the mite infestation, the dose can be doubled, i.e., 1–2 mg milbemycin oxime per kg bodyweight, always given daily as a single dose.

Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*)
The recommended dosage is 1.0–1.5 mg/kg every other day for a total of 8 treatments.

Treatment of nose mites (*Pneumonyssoides caninum*)
For the treatment of *Pneumonyssoides caninum*, the recommended dosage is 0.5–1.0 mg/kg three times in one-week intervals.

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

On very rare occasions general symptoms of intoxication have been reported such as: depression, hypersalivation, tremor and ataxia. The signs disappeared spontaneously, usually within a day. No antidote is known.

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

<To be completed in accordance with national requirements.>

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QP54AB01

4.2 Pharmacodynamics

Milbemycin oxime belongs to the group of macrocyclic lactones, isolated from the fermentation of *Streptomyces hygroscopicus* var. *aureolacrimosus*. Milbemycin oxime is effective against larval stages of L3 and L4 and against microfilariae of *Dirofilaria immitis*, as well as against the following nematodes: *Toxocara canis*, *Toxocascaris leonina*, *Trichuris vulpis*, *Ancylostoma caninum*,

Angiostrongylus vasorum and *Crenosoma vulpis*. Furthermore, it is also effective against the mites *Demodex canis*, *Sarcoptes scabiei* var. *canis*, and *Pneumonyssoides caninum*.
The activity of milbemycin oxime is related to its action on invertebrate neurotransmission. Milbemycin oxime 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.

4.3 Pharmacokinetics

After oral administration of milbemycin oxime in dogs, peak plasma levels occur at about 2–4 hours, and decline with a half-life of the unmetabolised milbemycin oxime of 1–4 days. Bioavailability is about 80 %.
In the rat, metabolism appears to be complete although slow, since unchanged milbemycin oxime has not been found in urine or faeces. Main metabolites in the rat are monohydroxylated derivatives, attributable to hepatic biotransformation. In addition to relatively high liver concentrations, there is some concentration in fat, reflecting its lipophilicity.

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Double-sided aluminium blisters consisting of aluminium forming and lidding foils in a cardboard box.

Available pack sizes:
1 box with 1 blister containing 6 tablets.
1 box with 2 blisters, each blister contains 4 tablets.
1 box with 5 blisters, each blister contains 6 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.

This veterinary medicinal product should not enter water courses as milbemycin oxime 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

<To be completed nationally.>

7. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally.>

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}> <{DD month YYYY}.>

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

{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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Interceptor Flavor 2.3 mg tablets for dogs
Interceptor Flavor 5.75 mg tablets for dogs
Interceptor Flavor 11.5 mg tablets for dogs
Interceptor Flavor 23 mg tablets for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 2.3 mg milbemycin oxime.
Each tablet contains 5.75 mg milbemycin oxime.
Each tablet contains 11.5 mg milbemycin oxime.
Each tablet contains 23 mg milbemycin oxime.

3. PACKAGE SIZE

6 tablets
8 tablets
30 tablets

4. TARGET SPECIES

For very small dogs up to 4.5 kg.
For small dogs from 5 to 11 kg.
For medium dogs from 12 to 22 kg.
For large dogs from 23 to 45 kg.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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 OF THE MARKETING AUTHORISATION HOLDER

<To be completed nationally.>

14. MARKETING AUTHORISATION NUMBERS

<To be completed nationally.>

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

DOUBLE-SIDED ALUMINIUM BLISTERS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Interceptor Flavor

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.3 mg milbemycin oxime
5.75 mg milbemycin oxime
11.5 mg milbemycin oxime
23 mg milbemycin oxime

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Interceptor Flavor 2.3 mg tablets for dogs
Interceptor Flavor 5.75 mg tablets for dogs
Interceptor Flavor 11.5 mg tablets for dogs
Interceptor Flavor 23 mg tablets for dogs

2. Composition

Each tablet contains:

Active substance:
Milbemycin oxime

Product	Milbemycin oxime
2.3 mg tablet for very small dogs	2.3 mg
5.75 mg tablet for small dogs	5.75 mg
11.5 mg tablet for medium dogs	11.5 mg
23 mg tablet for large dogs	23 mg

Interceptor Flavor 2.3 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “RN” and no imprint on the other side.

Interceptor Flavor 5.75 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “GO” and no imprint on the other side.

Interceptor Flavor 11.5 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “FKF” and no imprint on the other side.

Interceptor Flavor 23 mg tablets: Light brown, round, biconvex tablets, imprinted on one side with the letters “FRF and no imprint on the other side.

3. Target species

Dog.

4. Indications for use

The product is indicated for
- the prevention of heartworm disease in dogs (*Dirofilaria immitis*),
- the treatment of intestinal worms such as whipworms (*Trichuris vulpis*), roundworms (*Toxocara canis*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*) and
- the treatment of lungworms (*Crenosoma vulpis*) and the French heartworm (*Angiostrongylus vasorum*).

It is also indicated for
- the treatment of generalised demodicosis (*Demodex canis*),
- the treatment of mange induced by *Sarcoptes scabiei* var. *canis* and

- the treatment of nose mites (*Pneumonyssoides caninum*).

5. Contraindications

Dot not use in puppies under 2 weeks of age.
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 warnings

Special warnings:
As relapses in the case of generalised demodicosis are quite common, continued monitoring by a veterinarian is recommended after clinical signs have ceased.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
Unnecessary use of antiparasitics or use deviating from the instructions given in the package leaflet 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/infestation based on its epidemiological features, for each individual animal.
Based on the diagnosis and recommendations by the responsible veterinarian, dogs and cats living in the same household may need to be treated with a suitable worm control product.

Special precautions for safe use in the target species:
The treatment of animals weighing less than 1 kg should be based on a benefit-risk evaluation.

This product contains milbemycin oxime, a macrocyclic lactone. Studies with milbemycin oxime indicated that the safety margin for Collies and related breeds is narrower than for other dog breeds. Therefore, the recommended dose should be complied with. The clinical signs in Collies and related breeds are similar to those observed in the general population of dogs when overdosed. In studies performed with milbemycin oxime, when given monthly at the recommended dose, no reaction of intolerance has been observed in more than 75 strains of dogs including Collies. The tolerance of milbemycin oxime in young puppies from these breeds has not been investigated.

No studies have been performed with debilitated dogs or dogs with seriously compromised kidney or liver function. Therefore, the product should be only used in debilitated animals after a benefit-risk evaluation by the responsible veterinarian.

During treatment of generalised demodicosis, especially with debilitated dogs, vomiting, diarrhoea, and somnolence can be observed. If the signs persist for longer than 48 hours, a reduction of the applied dose is recommended. If convulsion or ataxia is observed, treatment should be immediately discontinued until signs resolve and a veterinarian should be consulted for further treatment options.

The treatment of dogs with high numbers of circulating microfilariae can sometimes provoke a transient hypersensitivity reaction. The clinical signs e.g., pale mucous membrane, vomiting, tremors, laboured breathing and hypersalivation can be attributed to the release of toxic proteins from dead or immobilized microfilariae and are not due to any direct toxic effect of the veterinary product. Symptomatic treatment is recommended.

Therefore, before initiation of treatment with the product, especially in heartworm-risk areas or in case it is known that a dog has been travelling to and from heartworm risk regions, any concurrent infestation of *Dirofilaria immitis*, should be excluded. In the case when microfilariae are present and before application of the product, an adulticide therapy is recommended. Please refer to section “Adverse events” for hypersensitivity reactions.

The chewable 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:
Wash hands after handling the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

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 milbemycin oxime at a dose rate of 0.5 mg/kg. 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:
On very rare occasions general symptoms of intoxication have been reported such as: depression, hypersalivation, tremor and ataxia. The signs disappeared spontaneously, usually within a day. No antidote is known.

Special restrictions for use and special conditions for use:
<To be completed in accordance with national requirements.>

Major incompatibilities:
Not applicable.

7. Adverse events

Target species: Dog

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting[1,2], Diarrhoea[1], Hypersalivation[2]
Hypersensitivity reaction[3]
Somnolence[1], Seizure[4], Tremors[2]
Laboured breathing[2]
Ataxia[4], Pale mucous membrane[2]

[1] During treatment of generalised demodicosis, especially in debilitated dogs. If the signs persist for longer than 48 hours, a reduction of the applied dose is recommended.
[2] Can be attributed to the release of toxic proteins from dead or immobilized microfilariae and are not due to any direct toxic effect of the veterinary product.
[3] The treatment of dogs with high numbers of circulating microfilariae can sometimes provoke a transient reaction. See also section 3.5.
[4] If these signs occur, treatment should be immediately discontinued until signs resolve and a veterinarian should be consulted for further treatment options.

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: {national system details listed in Appendix I}.

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

Oral use.
The product is available in four strengths.
The recommended minimum dose is 0.5 mg milbemycin oxime per kg bodyweight, this corresponds to:

Body weight	Product	Strength (Milbemycin oxime / tablet)
up to 4.5 kg	One 2.3 mg tablet for very small dogs	2.3 mg
from 5 to 11 kg	One 5.75 mg tablet for small dogs	5.75 mg
from 12 to 22 kg	One 11.5 mg tablet for medium dogs	11.5 mg
from 23 to 45 kg	One 23 mg tablet for large dogs	23.0 mg

Prevention of heartworm disease (caused by *Dirofilaria immitis*)
Dogs in areas endemic for heartworm, or those, which have travelled to such areas, may be infected with adult heartworms. Prior to treatment with the product, the advice in section 'Special precautions for safe use in the target species' should be considered.
A single dose of 0.5–1.0 mg/kg is applied orally once per month, ideally always at the same day of the month.

For prevention of dirofilariosis, the treatment must be repeated every month. The first dose should be given within 30 days after the onset of and terminating 30 days after the end of the mosquito season. In case that an interval would exceed 30 days, immediately resume treatment at the prescribed dose. If the interruption would be greater than 60 days, a veterinarian should be consulted before resuming the treatment with the product.

The product, when substituting other products for the prevention of dirofilariosis, should be administered within 30 days after the last treatment.

In non-endemic areas, there should be no risk of dogs having heartworms and they can be treated according to the local epidemiological situation.

Treatment of intestinal stages of whipworms (*Trichuris vulpis*), roundworms (*Toxocara canis*, *Toxacaris leonina*) and hookworms (*Ancylostoma caninum*)
The product is administered orally in a single dose of 0.5–1.0 mg/kg.

Treatment of lungworms (*Crenosoma vulpis*)
For *Crenosoma vulpis*, the product is administered orally in a single dose of 0.5–1.0 mg/kg.

Treatment of French heartworm (*Angiostrongulus vasorum*)
For *Angiostrongulus vasorum* infections, the product should be given orally in a single dose of 0.5–1.0 mg/kg four times at weekly intervals.

Treatment of generalised demodicosis (caused by *Demodex canis*)

The recommended dose is 0.5–1.0 mg/kg per day until two negative cutaneous scrapings are achieved within a month.
If it is justified by the clinical status and by the mite infestation, the dose can be doubled, i.e., 1–2 mg milbemycin oxime per kg bodyweight, always given daily as a single dose.

Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*)
The recommended dosage is 1.0–1.5 mg/kg every other day for a total of 8 treatments.

Treatment of nose mites (*Pneumonyssoides caninum*)
For the treatment of *Pneumonyssoides caninum*, the recommended dosage is 0.5–1.0 mg/kg three times in one-week intervals.

9. Advice on correct administration

The tablets should be administered orally in a single dose and may be given with or after some food.

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 storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton 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.

This veterinary medicinal product should not enter water courses as milbemycin oxime 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

<To be completed nationally.>

Available pack sizes:
1 box with 1 blister containing 6 tablets.
1 box with 2 blisters, each blister contains 4 tablets.
1 box with 5 blisters, each blister contains 6 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{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:
<To be completed nationally.>

Manufacturer responsible for batch release:
Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France