# INTERCEPTOR FLAVOR TABS- milbemycin oxime tablet Elanco US Inc.

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# $Interceptor^{TM}$

(milbemycin oxime)

#### INFORMATION FOR DOSING DOGS

The palatable once-a-month tablet that prevents heartworm disease, controls adult hookworm, and removes and controls adult roundworm and whipworm infections in dogs and puppies.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of the reach of children.

# Description:

INTERCEPTOR is available in four tablet sizes in color-coded packages for oral administration to dogs and puppies. Each tablet is formulated to provide a minimum of 0.23 mg/lb (0.5 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydromilbemycins in the ratio of approximately 80%  $A_4$  ( $C_{32}H_{45}NO_7$ , MW 555.71) and 20%  $A_3$  ( $C_{31}H_{43}NO_7$ , MW 541.68).

Package color	Milbemycin oxime tablet
Brown	2.3 mg*
Green	5.75 mg
Yellow	11.5 mg
White	23.0 mg

<sup>\*</sup>for dogs only

#### **Indications:**

INTERCEPTOR is indicated for use in the prevention of heartworm disease caused by *Dirofilaria immitis*, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis* and *Toxascaris leonina* (roundworms) and *Trichuris vulpis* (whipworm) infections in dogs and in puppies four weeks of age or greater and two pounds body weight or greater.

#### Dosage:

INTERCEPTOR is given orally, once a month, at the recommended minimum dosage rate of 0.23 mg milbemycin oxime per pound of body weight (0.5 mg/kg).

# **Recommended Dosage Schedule for Dogs**

Body Weight	INTERCEPTOR
2-10 Ibs.	One tablet (2.3 mg)
11-25 Ibs.	One tablet (5.75 mg)
26-50 Ibs.	One tablet (11.5 mg)
51-100 Ibs.	One tablet (23.0 mg)

Dogs over 100 lbs. are provided the appropriate combination of tablets.

#### Administration:

INTERCEPTOR is palatable and most dogs will consume the tablet willingly when offered by the owner. As an alternative, the dual-purpose tablet may be offered in food or administered as other tablet medications. Watch the dog closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

INTERCEPTOR must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the dog's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer INTERCEPTOR immediately and resume the monthly dosing schedule.

If INTERCEPTOR replaces diethylcarbamazine (DEC) for heartworm prevention, the first dose must be given within 30 days after the last dose of DEC.

# **Palatability:**

Palatability trials conducted in 244 dogs from 10 different U.S. veterinary practices demonstrated that INTERCEPTOR was willingly accepted from the owner by over 95% of dogs. The trial was comprised of dogs representing 60 different breeds and both sexes, with weights ranging from 2.1 lbs. to 143.3 lbs., and ages ranging from 8 weeks to 15 years.

#### **Precautions:**

Do not use in puppies less than four weeks of age or less than two pounds of body weight. Prior to initiation of the INTERCEPTOR treatment program, dogs should be tested for existing heartworm infections. Infected dogs should be treated to remove adult heartworms and microfilariae prior to initiating treatment with INTERCEPTOR. Mild, transient hypersensitivity reactions manifested as labored respiration, vomiting, salivation and lethargy, have been noted in some treated dogs carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae.

#### **Adverse Reactions:**

The following adverse reactions have been reported following the use of INTERCEPTOR: Depression/lethargy, vomiting, ataxia, anorexia, diarrhea, convulsions, weakness and hypersalivation.

# **Efficacy:**

INTERCEPTOR eliminates the tissue stage of heartworm larvae and the adult stage of hookworm (*Ancylostoma caninum*), roundworms (*Toxocara canis*, *Toxascaris leonina*) and whipworm (*Trichuris vulpis*) infestations when administered orally according to the recommended dosage schedule. The anthelmintic activity of milbemycin oxime is believed to be a result of interference with invertebrate neurotransmission.

# **Safety:**

Milbemycin oxime has been tested safely in over 75 different breeds of dogs, including collies, pregnant females, breeding males and females, and puppies over two weeks of age. In well-controlled clinical field studies, 786 dogs completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, antibiotics, steroids, flea collars, shampoos and dips.

Two studies in heartworm-infected dogs were conducted which demonstrated mild, transient

hypersensitivity reactions in treated dogs with high microfilaremia counts (see Precautions for reactions observed). Safety studies in pregnant dogs demonstrated that high doses (1.5 mg/kg =3X) of milbemycin oxime given in an exaggerated dosing regimen (daily from mating through weaning), resulted in measurable concentrations of the drug in milk. Puppies nursing these females which received exaggerated dosing regimens demonstrated milbemycin-related effects. These effects were directly attributable to the exaggerated experimental dosing regimen. The product is normally intended for once-a-month administration only. Subsequent studies included using 3X daily from mating to one week before weaning and demonstrated no effects on the pregnant females or their litters. A second study where pregnant females were dosed once at 3X the monthly use rate either before, on the day of or shortly after whelping resulted in no effects on the puppies.

Some nursing puppies, at 2, 4, and 6 weeks of age, given greatly exaggerated oral milbemycin oxime doses (9.6 mg/kg = 19X) exhibited signs typified by tremors, vocalization and ataxia. These effects were all transient and puppies returned to normal within 24 to 48 hours. No effects were observed in puppies given the recommended dose of milbemycin oxime (0.5 mg/kg). This product has not been tested in dogs less than 1 kg weight.

A rising-dose safety study conducted in rough-coated collies, manifested a clinical reaction consisting of ataxia, pyrexia and periodic recumbency, in one of fourteen dogs treated with milbemycin oxime at 12.5 mg/kg (25X monthly use rate). Prior to receiving the 12.5 mg/kg dose (25X monthly use rate) on day 56 of the study, all animals had undergone an exaggerated dosing regimen consisting of 2.5 mg/kg milbemycin oxime (5X monthly use rate) on day 0, followed by 5.0 mg/kg (10X monthly use rate) on day 14 and 10.0 mg/kg (20X monthly use rate) on day 32. No adverse reactions were observed in any of the collies treated with this regimen up through the 10.0 mg/kg (20X monthly use rate) dose.

# How supplied:

INTERCEPTOR is available in four tablet sizes (see Dosage section), formulated according to the weight of the dog. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 10 per display carton.

# **Storage conditions:**

INTERCEPTOR should be stored at room temperature, between 59° and 77°F (15-25°C).

#### INFORMATION FOR DOSING CATS

The palatable once-a-month tablet that prevents heartworm disease and removes adult roundworms and hookworms in cats and kittens.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of the reach of children.

# Description:

INTERCEPTOR for Cats is available in three tablet sizes in color-coded packages for oral administration to cats and kittens. Each tablet is formulated to provide a minimum of 0.9 mg/lb (2.0 mg/kg) body weight of milbemycin oxime. Milbemycin oxime consists of the oxime derivatives of 5-didehydromilbemycins in the ratio of approximately 80%  $A_4$  ( $C_{32}H_{45}NO_7$ , MW 555.71) and 20%  $A_3$  ( $C_{31}H_{43}NO_7$ , MW 541.68).

#### **Indications:**

INTERCEPTOR for Cats is indicated for use in the prevention of heartworm disease caused by

*Dirofilaria immitis*, and the removal of adult *Ancylostoma tubaeforme* (hookworm) and *Toxocara cati* (roundworm) in cats and kittens six weeks of age or greater and 1.5 lbs. body weight or greater.

# Dosage:

INTERCEPTOR for Cats is given orally, once a month, at the recommended minimum dosage rate of 0.9 mg milbemycin oxime per pound of body weight (2.0 mg/kg).

# **Recommended Dosage Schedule for Cats**

Body Weight	INTERCEPTOR
1.5 to 6 lbs.	One tablet (5.75 mg)
6.1-12 Ibs.	One tablet (11.5 mg)
12.1-25 Ibs.	One tablet (23.0 mg)

Cats over 25 lbs. are provided the appropriate combination of tablets.

#### Administration:

INTERCEPTOR for Cats is palatable and may be offered by the owner as a treat. As an alternative, the tablet may be offered in food or administered as other tablet medications. The tablets can be broken for ease of administration. Watch the cat closely following dosing to be sure the entire dose has been consumed. If it is not entirely consumed, redose once with the full recommended dose as soon as possible.

INTERCEPTOR for Cats must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the cat's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. If a dose is missed and a 30-day interval between dosing is exceeded, administer INTERCEPTOR for Cats immediately and resume the monthly dosing schedule. It is recommended that cats be tested for existing heartworm infection prior to starting treatment with INTERCEPTOR for Cats (see Precautions).

# **Palatability:**

Palatability trials conducted in 72 cats demonstrated that cats were successfully dosed with INTERCEPTOR for Cats by the owner when they either offered the tablet as a treat, placed the tablet in the cat's mouth or placed the tablet in the cat's food in 72% of cats. About 16% of the cats were dosed manually and 13% of the cats were not successfully dosed according to the protocol.

#### **Precautions:**

Do not use in kittens less than six weeks of age or less than 1.5 lbs. body weight. Safety in heartworm-positive cats has not been established. Safety in breeding, pregnant, and lactating queens and breeding toms has not been established.

#### **Efficacy:**

INTERCEPTOR for Cats eliminate the tissue stage of heartworm larvae and hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections when administered orally according to the recommended dosage schedule. The anthelmintic activity of milbemycin oxime is believed to be a result of interference with invertebrate neuro- transmission.

# Safety:

Milbemycin oxime has been tested safely in over 8 different breeds of cats. In well-controlled clinical field studies 141 cats completed treatment with milbemycin oxime. Milbemycin oxime was used safely in animals receiving frequently used veterinary products such as vaccines, anthelmintics, anesthetics, antibiotics, steroids, flea collars, shampoos and dips.

Safety studies were conducted in young cats and kittens and doses of 1X, 3X and 5X the minimum recommended dose of 2.0 mg/kg demonstrated no drug-related effects. Tolerability studies at exaggerated doses of 1OX also demonstrated no drug-related adverse effects in kittens and young adult cats.

# How supplied:

INTERCEPTOR for Cats is available in three tablet sizes (see Dosage section), formulated according to the weight of the cat. Each tablet size is available in color-coded packages of 6 or 12 tablets each, which are packaged 10 per display carton.

# Storage conditions:

INTERCEPTOR for Cats should be stored at room temperature, between 59° and 77°F (15-25°C).

Manufactured for: Elanco US Inc.

Greenfield, IN 46140, USA

NADA #140-915, Approved by FDA

PA100030AMX PCR-750-09204

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# Principal Display Panel - Interceptor 2.3 mg Box Label

Interceptor<sup>TM</sup>

(milbemycin oxime)

Product # 616159



# Principal Display Panel - Interceptor 2.3 mg Carton Label

# $Interceptor^{\text{TM}}$

(milbemycin oxime)

# BROAD SPECTRUM PARASITICIDE

Contains once-a-month flavored tablets to prevent **heartworm** disease, control adult **hookworm** infection, and remove and control adult **roundworms** and **whipworms** in dogs and puppies.

6 PACK

For dogs 2-10 lbs.

Net contents: 6 tablets. 2.3 mg each.

Product #616159 NADA #140-915, Approved by FDA.

### Keep this and all drugs out of the reach of children.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**Elanco**<sup>TM</sup>



Veterinarian's imprint here



Enclosed insert describes use, directions and precautions to follow when administering INTERCEPTOR

Place treatment reminder stickers on your calendar for each of the months following the date of the initial treatment.

If you have any questions concerning the use of this product, contact your veterinarian.

To report adverse effects, access medical information, or obtain additional product information call 1-888-545-5973

www.InterceptorPet.com

Product of Japan

Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA

Storage Conditions: INTERCEPTOR should be stored at room temperature,

between 59° and 77°F (15°-25°C).

Elanco, interceptor and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

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cluct #616159 NADA #140-915, Approved by FDA.

Keep this and all drugs out of the reach of children. Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Elanco





# Principal Display Panel - Interceptor 2.3 mg Blister Label

INTERCEPTOR<sup>TM</sup>

(milbemycin oxime)

For dogs 2-10 lbs.

LOT XXXXXXXX

**EXPIRATION 00/00** 

2.3 mg

Elanco

# INTERCEPTOR™ (milbemycin oxime)

For dogs 2-10 lbs.

Jan. or July

LOT XXXXXXXXX EXPIRATION 00/00 2.3 mg



Elanco

Principal Display Panel - Interceptor 5.75 mg Box Label Interceptor  $^{\text{TM}}$ 

(milbemycin oxime)

Product # 616162





For dogs 11-25 lbs.









Manufactured for: Elance US Inc. Greenfield, IN 46401, USA. Product of Japan To report adverse effects, access medical information, or obtain additional product information call 1-888-545-5973

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Storage Conditions: INTERCEPTOR should be stored at room temperatur between 59° and TOPE (15-25°C). SMODICCOAND

# Principal Display Panel - Interceptor 5.75 mg Carton Label

# Interceptor<sup>TM</sup>

(milbemycin oxime)

# BROAD SPECTRUM PARASITICIDE

Contains once-a-month flavored tablets to prevent **heartworm** disease, control adult **hookworm** infection, and remove and control adult **roundworms** and **whipworms** in dogs and puppies, and to prevent heartworm disease and remove adult hookworms and roundworms in cats and kittens.

6 PACK

For dogs 11-25 lbs.

For cats 1.5-6 lbs

Net contents: 6 tablets. 5.75 mg each.

Product #616160 NADA #140-915, Approved by FDA.

# Keep this and all drugs out of the reach of children.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**Elanco**<sup>TM</sup>



EXE 107





Enclosed insert describes use, directions and precautions to follow when administering INTERCEPTOR. Place treatment reminder stickers on your calendar for each of the months following the date of the initial treatment.

If you have any questions concerning the use of this product, contact your veterinarian. To report adverse effects, access medical information, or obtain additional product information call 1-888-545-5973

www.InterceptorPet.com

Product of Japan

PACK

Manufactured for: Flanco US Inc. Greenfield. IN 46140. USA

Storage Conditions: INTERCEPTOR should be stored at room temperature,

between 59° and 77°F (15°-25°C).



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#### **BROAD SPECTRUM** PARASITICIDE

Contains once-a-month flavored tablets to prevent heartworm disease, control adult hookworm infection, and remove and control adult roundworms and whipworms in dogs and puppies, and to prevent heartworm disease and remove adult hookworms and roundworms in cats and kittens. 6



For dogs 11-25 lbs. For cats 1.5-6 lbs.

Product M616160 NADA #140-915, Approved by FDA. Keep this and all drugs out of the reach of children. Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.









# Principal Display Panel - Interceptor 5.75 mg Blister Label

INTERCEPTOR<sup>TM</sup>

(milbemycin oxime)

For dogs 11-25 lbs. and for cats 1.5-6 lbs.

LOT XXXXXXXX

**EXPIRATION 00/00** 

5.75 mg

Elanco

# INTERCEPTOR™

(milbemycin oxime)

For dogs 11-25 lbs. and for cats 1.5-6 lbs.

Jan. or July

LOT EXPIRATION 5.75 mg



Elanco

Principal Display Panel - Interceptor 11.5 mg Box Label Interceptor  $^{\text{TM}}$ 

(milbemycin oxime)

Product # 616160



Product #616162





For dogs 51-100 lbs. For cats 12.1-25 lbs.









Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA

Product of Japan
To report adverse

To report adverse effects, access medical information, or obtain additional product information call 1-888-545-5913

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Storage Conditions: IMTERCEPTOR should be stored at room temperature, between 59° and 77°F (15-25°C). SH100027AMB

# Principal Display Panel - Interceptor 11.5 mg Carton Label

# Interceptor<sup>TM</sup>

(milbemycin oxime)

# BROAD SPECTRUM PARASITICIDE

Contains once-a-month flavored tablets to prevent **heartworm** disease, control adult **hookworm** infection, and remove and control adult **roundworms** and **whipworms** in dogs and puppies, and to prevent heartworm disease and remove adult hookworms and roundworms in cats and kittens.

6 PACK

For dogs 26-50 lbs.

For cats 6.1-12 lbs.

Net contents: 6 tablets. 11.5 mg each.

Product #616161 NADA #140-915, Approved by FDA.

# Keep this and all drugs out of the reach of children.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**Elanco**<sup>TM</sup>





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Enclosed insert describes use, directions and precautions to follow when administering INTERCEPTOR. Place treatment reminder stickers on your calendar for each of the months following the date of the initial treatment.

If you have any questions concerning the use of this product, contact your veterinarian.

To report adverse effects, access medical information, or obtain additional product information call 1-888-545-5973

www.InterceptorPet.com

Product of Japan

Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA

Storage Conditions: INTERCEPTOR should be stored at room temperature,

between 59° and 77°F (15°-25°C)



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# Principal Display Panel - Interceptor 11.5 mg Blister Label

INTERCEPTOR™

(milbemycin oxime)

For dogs 26-50 lbs. and for cats 6.1-12 lbs.

LOT

**EXPIRATION** 

11.5 mg

Elanco

# INTERCEPTOR™ (milbemycin oxime)

For dogs 51-100 lbs. and for cats 12.1-25 lbs.

Jan. or July

LOT EXPIRATION 23.0 mg



Principal Display Panel - Interceptor 23 mg Box Label Interceptor  $^{\text{TM}}$ 

(milbemycin oxime)

Product # 616161







For dogs 26-50 lbs.









Manufactured for: Elance US Inc. Greenfield, 19 66400, USA Profuct of Japan To report Japan To report Japan Information, or obtain additional product information cell 1-880-545-5973 tianco, interceptor and the diagonal ba are trademarks owned or licensed by Eli Lifly and Company, its subsidiaries or affiliates.

Starage Conditions: INTERCEPTOR should be stored at room temperature, between 59° and 77°F (15°25°C SH100025AMB PCR-720-09210

# Principal Display Panel - Interceptor 23 mg Carton Label

# Interceptor<sup>TM</sup>

(milbemycin oxime)

# BROAD SPECTRUM PARASITICIDE

Contains once-a-month flavored tablets to prevent **heartworm** disease, control adult **hookworm** infection, and remove and control adult **roundworms** and **whipworms** in dogs and puppies, and to prevent heartworm disease and remove adult hookworms and roundworms in cats and kittens.

6 PACK

For dogs 51-100 lbs.

For cats 12.1-25 lbs

Net contents: 6 tablets. 23.0 mg each.

Product #616162 NADA #140-915, Approved by FDA.

# Keep this and all drugs out of the reach of children.

**Caution:** Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

**Elanco**<sup>TM</sup>





101





Enclosed insert describes use, directions and precautions to follow when administering INTERCEPTOR. Place treatment reminder stickers on your calendar for each of the months following the date of the initial treatment.

If you have any questions concerning the use of this product, contact your veterinarian. To report adverse effects, access medical information, or obtain additional product information call 1-888-545-5973

www.InterceptorPet.com

Product of Japan

Manufactured for: Elanco US Inc. Greenfield, IN 46140, USA

Storage Conditions: INTERCEPTOR should be stored at room temperature,

between 59° and 77°F (15°-25°C).



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#### **BROAD SPECTRUM** PARASITICIDE

Contains once-a-month flavored tablets to prevent heartworm disease control adult hookworm infection, and remove and control adult roundworms and whipworms in dogs and puppies, and to prevent heartworm disease and remove adult hookworms and roundworms in cats and kittens. 6





roduct #616161 MADA #140-915, Approved by FDA. eep this and all drugs out of the reach of children





PACK





# Principal Display Panel - Interceptor 23 mg Blister Label

INTERCEPTOR<sup>TM</sup>

(milbemycin oxime)

For dogs 51-100 lbs. and for cats 12.1-25 lbs.

LOT

**EXPIRATION** 

23 mg

Elanco

# INTERCEPTOR™

(milbemycin oxime)

For dogs 26-50 lbs. and for cats 6.1-12 lbs.

Jan. or July

LOT EXPIRATION

11.5 mg





### INTERCEPTOR FLAVOR TABS

milbemycin oxime tablet

#### **Product Information**

Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:58198-2011

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Milbemycin Oxime (UNII: 0502PUN0GT) (Milbemycin Oxime - UNII:0502PUN0GT)	Milbemycin Oxime	2.3 mg

# Inactive Ingredients Ingredient Name Strength Lactose Monohydrate (UNII: EWQ57Q8I5X) Methyl Alcohol (UNII: Y4S76JWI15) Hydrogenated soybean oil (UNII: A2M9 1M9 18C) Castor Oil (UNII: D5340 Y219 G) croscarmellose sodium (UNII: M28OL1HH48) Silicon Dioxide (UNII: ETJ7Z6XBU4) Magnesium Stearate (UNII: 70097M6I30)

Product Characteristics				
Color	brown (Brown)	Score	no score	
Shape	ROUND (Round)	Size	6 mm	
Flavor	MEAT (MEAT)	Imprint Code	RN;CGV	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:58198-2011-1	1 in 1 BOX			
1	6 in 1 BLISTER PACK			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140915	07/21/1994	

# INTERCEPTOR FLAVOR TABS

milbemycin oxime tablet

<b>Product Information</b>			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58 19 8 - 20 12
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Milbemycin Oxime (UNII: 0502PUN0GT) (Milbemycin Oxime - UNII:0502PUN0GT)	Milbemycin Oxime	5.75 mg		

Inactive Ingredients		
Ingredient Name	Strength	
Lactose Monohydrate (UNII: EWQ57Q8I5X)		
Methyl Alcohol (UNII: Y4S76JWI15)		
Hydrogenated soybean oil (UNII: A2M91M918C)		
Castor Oil (UNII: D5340 Y2I9 G)		
croscarmellose sodium (UNII: M28OL1HH48)		
Silicon Dioxide (UNII: ETJ7Z6XBU4)		
Magnesium Stearate (UNII: 70097M6I30)		

Product Characteristics				
Color	brown (Brown)	Score	no score	
Shape	ROUND (Round)	Size	8mm	
Flavor	MEAT (MEAT)	Imprint Code	GO;CGV	
Contains				

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:58198-2012-1	1 in 1 BOX			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA140915	07/21/1994		

# INTERCEPTOR FLAVOR TABS

milbemycin oxime tablet

Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-2013	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name Basis of Strength Stren				
Milbemycin Oxime (UNII: 0502PUN0GT) (Milbemycin Oxime - UNII:0502PUN0GT)	Milbemycin Oxime	11.5 mg		

Inactive Ingredients					
Ingredient Name	Strength				
Lactose Monohydrate (UNII: EWQ57Q8I5X)					
Methyl Alcohol (UNII: Y4S76JWI15)					
Hydrogenated soybean oil (UNII: A2M91M918C)					
Castor Oil (UNII: D5340 Y2I9 G)					
croscarmellose sodium (UNII: M28OL1HH48)					
Silicon Dioxide (UNII: ETJ7Z6XBU4)					
Magnesium Stearate (UNII: 70097M6I30)					

Product Characteristics				
Color	brown (Brown)	Score	no score	
Shape	ROUND (Round)	Size	10 mm	
Flavor	MEAT (MEAT)	Imprint Code	FKF;CGV	
Contains				

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:58198-2013-1	1 in 1 BOX			
1		6 in 1 BLISTER PACK			

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140915	07/21/1994	

# INTERCEPTOR FLAVOR TABS

milbemycin oxime tablet

Droduct	Information
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Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Magnesium Stearate (UNII: 70097M6I30)

ı	8		
I	Ingredient Name	Basis of Strength	Strength
I	Milbemycin Oxime (UNII: 0502PUN0GT) (Milbemycin Oxime - UNII:0502PUN0GT)	Milbemycin Oxime	23.0 mg

# Inactive Ingredients Ingredient Name Strength Lactose Monohydrate (UNII: EWQ57Q8I5X) Methyl Alcohol (UNII: Y4S76JWI15) Hydrogenated soybean oil (UNII: A2M91M918C) Castor Oil (UNII: D5340 Y2I9G) croscarmellose sodium (UNII: M28OL1HH48) Silicon Dioxide (UNII: ETJ7Z6XBU4)

Product Characteristics				
Color	brown (Brown)	Score	no score	
Shape	ROUND (Round)	Size	14mm	
Flavor	MEAT (MEAT)	Imprint Code	FRF;CGV	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-2014-1	1 in 1 BOX		
1		6 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140915	07/21/1994	

# Labeler - Elanco US Inc. (966985624)

Establishment			
Name	Address	ID/FEI	Business Operations
Alps Pharmaceutical Ind. Co., Ltd.		717077197	API MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Alcami NC		832394535	MANUFACTURE

Establishment			
Name	Address	ID/FEI	Business Operations
Packaging Coordinators, Inc.		078525133	PACK, LABEL

Establishment			
Name	Address	ID/FEI	Business Operations
Elanco SAS France		736833104	MANUFACTURE

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