INTERCEPTOR PLUS- milbemycin oxime and praziquantel tablet, chewable Elanco US Inc.

INTERCEPTORTM

PLUS

(milbemycin oxime/praziquantel)

PA102228X

Caution

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

Description

INTERCEPTOR PLUS is available in four strengths in color-coded packages for oral administration to dogs and puppies according to their weight. Each chewable flavored tablet is formulated to provide a minimum of 0.23 mg/pound (0.5 mg/kg) of milbemycin oxime and 2.28 mg/pound (5 mg/kg) of praziquantel.

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). Milbemycin oxime is classified as a macrocyclic anthelmintic.

Praziquantel is an isoquinolone anthelmintic with the chemical name 2-(Cyclohexylcarbonyl)-1,2,3,6,7,-11b-hexahydro-4H-pyrazino [2,1-a]isoquinolin-4-one.

Indications

INTERCEPTOR PLUS is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis*; and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, *Echinococcus granulosus*, *and Dipylidium caninum*) infections in dogs and puppies two pounds of body weight or greater and six weeks of age and older.

Dosage and Administration

INTERCEPTOR PLUS should be administered orally, once every month, at the minimum dosage of 0.23 mg/lb (0.5 mg/kg) milbemycin oxime, and 2.28 mg/lb (5 mg/kg) praziquantel.

For heartworm prevention, give once monthly for at least 6 months after exposure to mosquitoes (see **EFFECTIVENESS**).

Dosage Schedule

	Milbemycin Oxime per	Praziquantel per	
Body Weight	chewable	chewable	Number of chewables
2 to 8 lbs.	2.3 mg	22.8 mg	One
8.1 to 25 lbs.	5.75 mg	57 mg	One
25.1 to 50 lbs.	11.5 mg	114 mg	One
50.1 to 100 lbs.	23 mg	228 mg	One
Over 100 lbs.	Administer the	appropriate combinatio	n of chewables.

INTERCEPTOR PLUS may be offered to the dog by hand or added to a small amount of dog food. The

chewables should be administered in a manner that encourages the dog to chew, rather than to swallow without chewing. Chewables may be broken into pieces and fed to dogs that normally swallow treats whole. Care should be taken that the dog consumes the complete dose, and treated animals should be observed for a few minutes after administration to ensure that no part of the dose is lost or rejected. If it is suspected that any of the dose has been lost, redosing is recommended.

Heartworm Prevention:

INTERCEPTOR PLUS should be administered at monthly intervals beginning within 1 month of the dog's first seasonal exposure to mosquitoes and continuing until at least 6 months after the dog's last seasonal exposure (see **EFFECTIVENESS**). INTERCEPTOR PLUS may be administered year-round without interruption. When switching from another heartworm preventative product to INTERCEPTOR PLUS, the first dose of INTERCEPTOR PLUS should be given within a month of the last dose of the former product.

Intestinal Nematode and Cestode Treatment and Control:

Dogs may be exposed to and can become infected with roundworms, whipworms, hookworms, and tapeworms throughout the year, regardless of season or climate. Clients should be advised of appropriate measures to prevent reinfection of their dog with intestinal parasites. Because the prepatent period for *E. multilocularis* may be as short as 26 days, dogs treated at the labeled monthly intervals may become reinfected and shed eggs between treatments.

Contraindications

There are no known contraindications to the use of INTERCEPTOR PLUS.

Warnings

Not for use in humans. Keep this and all drugs out of the reach of children.

Precautions

Treatment with fewer than 6 monthly doses after the last exposure to mosquitoes may not provide complete heartworm prevention (see **EFFECTIVENESS**).

Prior to administration of INTERCEPTOR PLUS, dogs should be tested for existing heartworm infections. At the discretion of the veterinarian, infected dogs should be treated to remove adult heartworms. INTERCEPTOR PLUS is not effective against adult *D. immitis*.

Mild, transient hypersensitivity reactions, such as labored breathing, vomiting, hypersalivation, and lethargy, have been noted in some dogs treated with milbemycin oxime carrying a high number of circulating microfilariae. These reactions are presumably caused by release of protein from dead or dying microfilariae.

Do not use in puppies less than six weeks of age.

Do not use in dogs or puppies less than two pounds of body weight.

The safety of INTERCEPTOR PLUS has not been evaluated in dogs used for breeding or in lactating females. Studies have been performed with milbemycin oxime alone (see **ANIMAL SAFETY**).

Adverse Reactions

The following adverse reactions have been reported in dogs after administration of milbemycin oxime or praziquantel: vomiting, diarrhea, depression/lethargy, ataxia, anorexia, convulsions, weakness, and salivation.

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Elanco US, Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

Information for Owner or Person Treating Animal:

Echinococcus multilocularis and *Echinococcus granulosus* are tapeworms found in wild canids and domestic dogs. *E. multilocularis* and *E. granulosus* can infect humans and cause serious disease (alveolar hydatid disease and hydatid disease, respectively).

Owners of dogs living in areas where *E. multilocularis* or *E. granulosus* are endemic should be instructed on how to minimize their risk of exposure to these parasites, as well as their dog's risk of exposure. Although INTERCEPTOR PLUS (milbemycine oxime/praziquantel) was 100% effective in laboratory studies in dogs against *E. multilocularis* and *E. granulosus*, no studies have been conducted to show that the use of this product will decrease the incidence of alveolar hydatid disease or hydatid disease in humans. Because the prepatent period for *E. multilocularis* may be as short as 26 days, dogs treated at the labeled monthly intervals may become reinfected and shed eggs between treatments.

Effectiveness

Heartworm Prevention:

In a well-controlled laboratory study, INTERCEPTOR PLUS was 100% effective against induced heartworm infections when administered once monthly for 6 consecutive months. In well-controlled laboratory studies, neither one dose nor two consecutive doses of INTERCEPTOR PLUS provided 100% effectiveness against induced heartworm infections.

Intestinal Nematodes and Cestodes Treatment and Control:

Elimination of the adult stage of hookworm (*Ancylostoma caninum*), roundworm (*Toxocara canis*, *Toxascaris leonina*), whipworm (*Trichuris vulpis*) and tapeworm (*Echinococcus multilocularis*, *Echinococcus granulosus*, *Taenia pisiformis and Dipylidium caninum*) infections in dogs was demonstrated in well-controlled laboratory studies.

Palatability

In a field study of 115 dogs offered INTERCEPTOR PLUS, 108 dogs (94.0%) accepted the product when offered from the hand as if a treat, 1 dog (0.9%) accepted it from the bowl with food, 2 dogs (1.7%) accepted it when it was placed in the dog's mouth, and 4 dogs (3.5%) refused it.

Animal Safety

INTERCEPTOR PLUS:

In a repeated dose safety study, 40 ten-week-old puppies (10 per group) were dosed with either a sham dose (0X) or 1, 3, or 5X the maximum label exposure of INTERCEPTOR PLUS every 14 days for a total of seven treatments. Ataxia, lethargy, and salivation were seen in the 3X and 5X treated dogs following each of the seven doses. Vomiting was seen in all treatment groups but had a higher incidence in the 3X and 5X treatment groups.

In a repeated dose safety study, 64 six-week-old puppies (16 per group) were dosed with either a sham dose (0X) or 1, 3, or 5X the maximum label exposure of INTERCEPTOR PLUS every 14 days for a total of four treatments. Lethargy was observed in all groups. Ataxia was observed in the three treated groups, including one dog in the 1X treated group. For both lethargy and ataxia the incidence and duration increased in the 3X and 5X groups. These signs were observed during the first 24 hours following treatment. Salivation and tremors were observed in the 3X and 5X treated dogs beginning

immediately after dosing and up to six hours post dose. Vomiting was only observed in the 5X treatment group on most, but not all, treatment days.

For INTERCEPTOR PLUS the maximum exposure based on product dosing is 2.5 mg/kg for milbemycin oxime and 25.1 mg/kg for praziquantel, which is higher than the minimum effective dose used in the safety studies for milbemycin oxime (see below).

Milbemycin Oxime:

Two studies were conducted in heartworm-infected dogs treated with milbemycin oxime. Mild, transient hypersensitivity reactions were observed in dogs with high microfilariae counts (see **PRECAUTIONS**).

Safety studies in pregnant dogs demonstrated that doses of 0.6X the maximum exposure dose of INTERCEPTOR PLUS, (1.5 mg/kg of milbemycin oxime), administered daily from mating through weaning, resulted in measurable concentrations of milbemycin oxime in milk. Puppies nursing these females demonstrated milbemycin oxime-related effects (depression, decreased activity, diarrhea, dehydration, nasal discharge). A subsequent study, which evaluated the daily administration of 0.6X the maximum exposure dose of INTERCEPTOR PLUS, from mating until one week before weaning, demonstrated no effects on the pregnant females or their litters. A study, in which pregnant females were dosed once, at 0.6X the maximum exposure dose of INTERCEPTOR PLUS 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, administered oral doses of 9.6 mg/kg milbemycin oxime (3.8X the maximum exposure dose of INTERCEPTOR PLUS) exhibited 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 administered 0.5 mg/kg milbemycin oxime (minimum label dose).

A rising-dose safety study conducted in rough-coated Collies resulted in ataxia, pyrexia, and periodic recumbency in one of fourteen dogs administered milbemycin oxime at 12.5 mg/kg (5X the maximum exposure dose of INTERCEPTOR PLUS). Prior to receiving the 12.5 mg/kg dose on day 56 of the study, all animals had undergone a dosing regimen consisting of 2.5 mg/kg milbemycin oxime on day 0, followed by 5.0 mg/kg on day 14, and 10.0 mg/kg on day 32. No adverse reactions were observed in any of the Collies treated with doses less than 12.5 mg/kg.

Storage Information

Store at room temperature, between 59° and 77°F (15-25°C).

How Supplied

INTERCEPTOR PLUS is available in four strengths, formulated according to the weight of the dog. Each strength is available in color-coded packages of six or twelve chewable tablets each. The tablets containing 2.3 mg milbemycin oxime/22.8 mg praziquantel or 5.75 mg milbemycin oxime/57 mg praziquantel are also available in color coded packages of one chewable tablet each.

Manufactured for: Elanco US Inc.

Greenfield, IN 46140, USA

Product of France

Approved by FDA under NADA # 141-338

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Revision date: October 2019

Principal Display Panel - Interceptor Plus 2-8 lbs Box Label

2-8 lbs

For dogs and puppies 2-8 lbs and 6 weeks of age and older

$INTERCEPTOR^{\tiny{TM}}$

PLUS

(milbemycin oxime/praziquantel)





For dogs and puppies 2–8 lbs and 6 weeks of age and older

2-8 lbs

2-8 lbs For dogs and puppies 2–8 lbs and 6 weeks of age and older



(milbemycin oxime/praziquantel)

Storage Conditions: Store at room temperature, between 59° and 77°F (15–25°C). Manufactured for: Binno US Inc. Greenfield, IN 45140, USA



Elanco



2-8 lbs



Principal Display Panel - Interceptor Plus 2-8 lbs 6 Pack Label

$INTERCEPTOR^{\mathsf{TM}}$

PLUS

(milbemycin oxime/praziquantel)

6

CHEWABLES

Each containing 2.3 mg milbemycin oxime and 22.8 mg praziquantel

For dogs and puppies 2-8 lbs and 6 weeks of age and older

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.**

2-8 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms





Principal Display Panel - Interceptor Plus 2-8 lbs 1 Chewable Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

1 CHEWABLE

Contains 2.3 mg milbemycin oxime and 22.8 mg praziquantel

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.**

For dogs and puppies 2–8 lbs and 6 weeks of age and older

2-8 lbs

BROAD-SPECTRUM PARASITICE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms

Elanco



Principal Display Panel - Interceptor Plus 2-8 lbs Blister Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

(2.3 mg milbemycin oxime+ 22.8 mg praziquantel)

A once-a-month chewable

For dogs and puppies 2-8 pounds and 6 weeks of age and older

LOT XXXXXXXX EXPIRATION XX/XX

Elanco

46186901

FL100437AMX



(milbemycin oxime/praziquantel)
(2.3 mg milbemycin oxime + 22.8 mg praziquantel)

A once-a-month chewable

For dogs and puppies 2-8 pounds and 6 weeks of age and older LOT XXXXXXXXX EXPIRATION XX/XX



46186901 FL100437AMX

Principal Display Panel - Interceptor Plus 8.1-25 lbs Box Label

8.1-25 lbs

For dogs and puppies 8.1–25 lbs and 6 weeks of age and older

INTERCEPTORTM

PLUS

(milbemycin oxime/praziquantel)





For dogs and puppies 8.1–25 lbs and 6 weeks of age and older

8.1-25 lbs

8.1-25 lbs



(milbemycin oxime/praziquantel)

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8.1-25 lbs



Principal Display Panel - Interceptor Plus 8.1-25 lbs 6 Pack Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

6

CHEWABLES

Each containing 5.75 mg milbemycin oxime and 57 mg praziquantel

For dogs and puppies 8.1-25 lbs and 6 weeks of age and older

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.**

8.1-25 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms





Principal Display Panel - Interceptor Plus 8.1-25 lbs 1 Chewable Label INTERCEPTOR $^{\rm TM}$

PLUS

(milbemycin oxime/praziquantel)

1 CHEWABLE

Contains 5.75 mg milbemycin oxime and 57 mg praziquantel

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.**

For dogs and puppies 8.1-25 lbs and 6 weeks of age and older

8.1-25 lbs

BROAD-SPECTRUM PARASITICE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms

Elanco



Principal Display Panel - Interceptor Plus 8.1-25 lbs Blister Label

INTERCEPTORTM

PLUS

(milbemycin oxime/praziquantel)

(5.75 mg milbemycin oxime+ 57 mg praziquantel)

A once-a-month chewable

For dogs and puppies 8.1-25 pounds and 6 weeks of age and older

LOT XXXXXXXX EXPIRATION XX/XX

Elanco

46186911

FL100469AMX



(milbemycin oxime/praziquantel) (5.75 mg milbemycin oxime+ 57 mg praziquantel) A once-a-month chewable

For dogs and puppies 8.1-25 pounds and 6 weeks of age and older LOT EXPIRATION



46186911 FL100469AMX

Principal Display Panel - Interceptor Plus 25.1-50 lbs Box Label

25.1-50 lbs

For dogs and puppies 25.1-50 lbs and 6 weeks of age and older

INTERCEPTORTM

PLUS

(milbemycin oxime/praziquantel)



INTERCEPTOR PLUS (milbemycin oxime/praziquantel)

25.1-50 lbs

25.1-50 lbs





Elanco



25.1-50 lbs

INTERCEPTOR PLUS (milbemycin oxime/praziquantel)

Principal Display Panel - Interceptor Plus 25.1-50 lbs 6 Pack Label

$INTERCEPTOR^{\tiny{TM}}$

PLUS

(milbemycin oxime/praziquantel)

6

CHEWABLES

Each containing 11.5 mg milbemycin oxime and 114 mg praziquantel

For dogs and puppies 25.1-50 lbs and 6 weeks of age and older

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.**

25.1-50 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms





Principal Display Panel - Interceptor Plus 25.1-50 lbs Blister Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

(11.5 mg milbemycin oxime+ 114 mg praziquantel)

A once-a-month chewable

For dogs and puppies 25.1-50 pounds and 6 weeks of age and older

LOT XXXXXXXX EXPIRATION XX/XX

Elanco

46186910

FL100467AMX



(milbemycin oxime/praziquantel)

(11.5 mg milbemycin oxime + 114 mg praziquantel)

A once-a-month chewable

For dogs and puppies 25.1-50 pounds and 6 weeks of age and older LOT EXPIRATION



46186910 FL100467AMX

Principal Display Panel - Interceptor Plus 50.1-100 lbs Box Label 50.1-100 lbs

For dogs and puppies 50.1-100 lbs and 6 weeks of age and older

INTERCEPTOR™

PLUS

(milbemycin oxime/praziquantel)





For dogs and puppies 50.1–100 lbs and 6 weeks of age and older

50.1-100 lbs

50.1—100 lbs
For dogs and puppies 50.1—100 lbs
and 6 weeks of age and older



(milbemycin oxime/praziquantel)

Storage Conditions: Shore all room temperature, between 59° and 77° F (15–25°C). Manufactured for: Banco IS Inc. Greenfield, IN 65MB, USA. Banco, Interceptor and the diagonal bar are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

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50.1-100 lbs

INTERCEPTORPLUS

(milbemycin oxime/praziquantel)

Principal Display Panel - Interceptor Plus 50.1-100 lbs 6 Pack Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

6

CHEWABLES

Each containing 23 mg milbemycin oxime and 228 mg praziquantel

For dogs and puppies 50.1-100 lbs and 6 weeks of age and older

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.**

50.1-100 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms





Principal Display Panel - Interceptor Plus 50.1-100 lbs Blister Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

(23 mg milbemycin oxime+ 228 mg praziquantel)

A once-a-month chewable

For dogs and puppies 50.1-100 pounds and 6 weeks of age and older

LOT XXXXXXXX EXPIRATION XX/XX

46186849

FL100468AMX



(milbemycin oxime/praziquantel)

(23 mg milbemycin oxime + 228 mg praziquantel)
A once-a-month chewable

For dogs and puppies 50.1-100 pounds and 6 weeks of age and older LOT EXPIRATION



46186849 FL100468AMX

Principal Display Panel - 12 Month Supply Label

INTERCEPTORTM

PLUS

(milbemycin oxime/praziquantel)

WITH INTERCEPTOR PLUS (MILBEMYCIN OXIME/PRAZIQUANTEL), ONE CONVENIENT CHEWABLE TABLET, EVERY MONTH, PROTECTS YOUR DOG AGAINST FIVE COMMON PARASITES.

Heartworm

Disease

Hookworm

Roundworm

Whipworm

Tapeworm



Principal Display Panel - Interceptor Plus 2-8 lbs 12 Carton Box Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

For dogs and puppies 2-8 lbs and 6 weeks of age and older

2-8 lbs

ElancoTM

Contains 5 12-count cartons



Principal Display Panel - Interceptor Plus 2-8 lbs 12 Pack Label INTERCEPTOR $^{\rm TM}$ $\rm PLUS$

(milbemycin oxime/praziquantel)

12

CHEWABLES

Each containing 2.3 mg milbemycin oxime and 22.8 mg praziquantel

For dogs and puppies 2-8 lbs and 6 weeks of age and older

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.**

2-8 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms



Principal Display Panel - Interceptor Plus 8.1-25 lbs 12 Carton Box Label INTERCEPTORTM

PLUS

(milbemycin oxime/praziquantel)

For dogs and puppies 8.1–25 lbs and 6 weeks of age and older

8.1-25 lbs

ElancoTM

Contains 5 12-count cartons



Principal Display Panel - Interceptor Plus 8.1-25 lbs 12 Pack Label INTERCEPTOR $^{\text{TM}}$ PLUS

(milbemycin oxime/praziquantel)

12

CHEWABLES

Each containing 5.75 mg milbemycin oxime and 57 mg praziquantel

For dogs and puppies 8.1-25 lbs and 6 weeks of age and older

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.**

8.1-25 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms



Principal Display Panel - Interceptor Plus 25.1-50 lbs 12 Carton Box Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

For dogs and puppies 25.1-50 lbs and 6 weeks of age and older

25.1-50 lbs

ElancoTM

Contains 5 12-count cartons



Principal Display Panel - Interceptor Plus 25.1-50 lbs 12 Pack Label INTERCEPTOR $^{\text{TM}}$ PLUS

(milbemycin oxime/praziquantel)

CHEWABLES

Each containing 11.5 mg milbemycin oxime and 114 mg praziquantel

For dogs and puppies 25.1-50 lbs and 6 weeks of age and older

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.**

25.1-50 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms



Principal Display Panel - Interceptor Plus 25.1-50 lbs Blister Label INTERCEPTOR

PLUS

(milbemycin oxime/praziquantel)

(11.5 mg milbemycin oxime+ 114 mg praziquantel)

A once-a-month chewable

For dogs and puppies 25.1-50 pounds and 6 weeks of age and older

Elanco

FL102228C



(milbemycin oxime/praziquantel)

(11.5 mg milbemycin oxime + 114 mg praziquantel)

A once-a-month chewable

For dogs and puppies 25.1-50 pounds and 6 weeks of age and older

Elanco

FL1022280

LOT:

EXP:

Principal Display Panel - Interceptor Plus 50.1-100 lbs Box Label INTERCEPTOR $^{\text{TM}}$

PLUS

(milbemycin oxime/praziquantel)

For dogs and puppies 50.1-100 lbs

and 6 weeks of age and older

50.1-100 lbs

ElancoTM

Contains 5 12-count cartons



Principal Display Panel - Interceptor Plus 50.1-100 lbs 12 Pack Label INTERCEPTOR $^{\text{TM}}$ PLUS

(milbemycin oxime/praziquantel)

12

CHEWABLES

Each containing 23 mg milbemycin oxime and 228 mg praziquantel

For dogs and puppies 50.1-100 lbs and 6 weeks of age and older

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.**

50.1-100 lbs

BROAD-SPECTRUM PARASITICIDE

Prevents heartworm disease

Treats and controls common intestinal parasites, including roundworms, hookworms, whipworms and tapeworms



PLUS

(milbemycin oxime/praziquantel)

(23 mg milbemycin oxime+ 228 mg praziquantel)

A once-a-month chewable

For dogs and puppies 50.1-100 pounds and 6 weeks of age and older

Elanco

FL102228D



(milbemycin oxime/praziquantel)

(23 mg milbemycin oxime + 228 mg praziquantel)

A once-a-month chewable

For dogs and puppies 50.1-100 pounds and 6 weeks of age and older

Elanco

FL102228D

LOT:

EXP:

INTERCEPTOR PLUS

milbemycin oxime and praziquantel tablet, chewable

Product Information

Product Type

PRESCRIPTION ANIMAL DRUG

Item Code (Source)

NDC:58198-5440

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
praziquantel (UNII: 6490C9U457) (praziquantel - UNII:6490C9U457)	praziquantel	22.8 mg

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYL GALLATE (UNII: 8 D4SNN7V92)			
STARCH, CORN (UNII: O8232NY3SJ)			
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)			
GLYCERIN (UNII: PDC6A3C0OX)			
SUCROSE (UNII: C151H8M554)			
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)			
BUTYLATED HYDRO XYANISO LE (UNII: REK4960 K2U)			

Product Characteristics				
Color	brown (brown)	Score	no score	
Shape	ROUND (ROUND)	Size	12mm	
Flavor	MEAT (MEAT)	Imprint Code		
Contains				

Packaging				
# Item C	o de	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58198-54	40-4 5 in	1 BOX		
1	2 in	1 CARTON		
1	6 in	1 BLISTER PACK		
2 NDC:58198-54	40-1 5 in	1 BOX		
2 NDC:58198-54	40-2 6 in	1 CARTON		
2	6 in	1 BLISTER PACK		
3 NDC:58198-54	40-3 1 in	1 CARTON		
3	1 in	1 BLISTER PACK		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141338	03/25/2015		

INTERCEPTOR PLUS

milbemycin oxime and praziquantel tablet, chewable

Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5444	
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
Praziquantel (UNII: 6490C9U457) (praziquantel - UNII:6490C9U457)	Praziquantel	57 mg

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM CHLORIDE (UNII: 451W47IQ8 X)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYL GALLATE (UNII: 8 D4SNN7V92)		
STARCH, CORN (UNII: O8232NY3SJ)		
BROWN IRON OXIDE (UNII: 1N032N7MFO)		
GLYCERIN (UNII: PDC6A3C0OX)		
SUCROSE (UNII: C151H8 M554)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
BUTYLATED HYDRO XYANISO LE (UNII: REK4960 K2U)		

Product Characteristics				
Color	brown (brown)	Score	no score	
Shape	ROUND (ROUND)	Size	17mm	
Flavor	MEAT (MEAT)	Imprint Code		
Contains				

Pā	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5444-4	5 in 1 BOX		
1		2 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:58198-5444-1	5 in 1 BOX		
2	NDC:58198-5444-2	6 in 1 CARTON		
2		6 in 1 BLISTER PACK		
3	NDC:58198-5444-3	1 in 1 CARTON		
3		1 in 1 BLISTER PACK		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA141338	03/25/2015		

INTERCEPTOR PLUS

milbemycin oxime and praziquantel tablet, chewable

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Product	Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5446
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
milbemycin oxime (UNII: 0502PUN0GT) (milbemycin oxime - UNII:0502PUN0GT)	milbemycin oxime	11.5 mg
Praziquantel (UNII: 6490C9U457) (praziquantel - UNII:6490C9U457)	Praziquantel	114 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
PROPYL GALLATE (UNII: 8 D4SNN7V92)	
STARCH, CORN (UNII: O8232NY3SJ)	
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCROSE (UNII: C151H8M554)	
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	

Product Characteristics

Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	20 mm
Flavor	MEAT (MEAT)	Imprint Code	
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Contains

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-5446-4	5 in 1 BOX		
1		2 in 1 CARTON		
1		6 in 1 BLISTER PACK		
2	NDC:58198-5446-1	5 in 1 BOX		
2	NDC:58198-5446-2	6 in 1 CARTON		

2	6 in 1 BLISTER PACK	
3 NDC:58198-5446-3	1 in 1 CARTON	
3	1 in 1 BLISTER PACK	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141338	03/25/2015	

INTERCEPTOR PLUS

milbemycin oxime and praziquantel tablet, chewable

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-5448
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
ı	Ingredient Name	Basis of Strength	Strength
ı	milbemycin oxime (UNII: 0502PUN0GT) (milbemycin oxime - UNII:0502PUN0GT)	milbemycin oxime	23 mg
ı	Praziquantel (UNII: 6490C9U457) (praziquantel - UNII:6490C9U457)	Praziquantel	228 mg

Inactive Ingredients	
Ingredient Name Streng	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
STARCH, CORN (UNII: O8232NY3SJ)	
BROWN IRON OXIDE (UNII: 1N0 32N7MFO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRO SE (UNII: C151H8 M554)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	

Product Characteristics			
Color	brown (brown)	Score	no score
Shape	ROUND (ROUND)	Size	29 mm
Flavor	MEAT (MEAT)	Imprint Code	
Contains			

Pack	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:58198-5448-4	5 in 1 BOX	
1		2 in 1 CARTON	
1		6 in 1 BLISTER PACK	
2	NDC:58198-5448-1	5 in 1 BOX	
2	NDC:58198-5448-2	6 in 1 CARTON	
2		6 in 1 BLISTER PACK	
3	NDC:58198-5448-3	1 in 1 CARTON	
3		1 in 1 BLISTER PACK	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NADA	NADA141338	03/25/2015			

Labeler - Elanco US Inc. (966985624)

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

Establishment						
Name	Address	ID/FEI	Business Operations			
PCAS		396133998	API MANUFACTURE			

Establishment				
Name	Address	ID/FEI	Business Operations	
GSK Consumer Health, Inc.		129836151	MANUFACTURE, PACK, LABEL	

Establishment				
Name	Address	ID/FEI	Business Operations	
Elanco Clinton Laboratories		039138631	PACK, LABEL	

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

Revised: 2/2020 Elanco US Inc.