

MILBEHART FLAVORED- milbemycin oxime tablet
Virbac AH, Inc.

MILBEHART™ (milbemycin oxime) Flavored Tablets

MILBEHART™

(milbemycin oxime)

Flavored Tablets

INFORMATION FOR DOSING DOGS

The 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: MILBEHART (milbemycin oxime) Flavored Tablets are 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-didehydromilbemycons in the ratio of approximately 80% A₄ (C₃₂H₄₅NO₇, MW 555.71) and 20% A₃ (C₃₁H₄₃NO₇, MW 541.68).

Package Color	Milbemycin oxime tablet
Yellow	2.3 mg*
Blue	5.75 mg
Purple	11.5 mg
Red	23.0 mg

*for dogs only

Indications: MILBEHART™ Flavored Tablets are 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: MILBEHART™ Flavored Tablets are 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	MILBEHART™ Flavored Tablets
2-10 lbs.	One tablet (2.3 mg)
11-25 lbs.	One tablet (5.75 mg)
26-50 lbs.	One tablet (11.5 mg)

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

Administration: MILBEHART™ Flavored Tablets are dual-purpose and 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.

MILBEHART™ Flavored Tablets must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the dogs 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 MILBEHART™ Flavored Tablets immediately and resume the monthly dosing schedule.

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

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 MILBEHART™ Flavored Tablets 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 MILBEHART™ Flavored Tablets. 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 MILBEHART™ Flavored Tablets: Depression/lethargy, vomiting, ataxia, anorexia, diarrhea, convulsions, weakness and hypersalivation.

Efficacy: MILBEHART™ Flavored Tablets eliminate 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: MILBEHART™ Flavored Tablets are 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 tablets each, which are packaged 10 per display carton.

Storage conditions: MILBEHART™ Flavored Tablets should be stored at room temperature, between 68° and 77°F (20-25°C).

Manufactured for:

Virbac AH, Inc.
P.O. Box 162059
Fort Worth, TX 76161
Phone: 1-800-338-3659

Made in Canada.

Approved by FDA under ANADA #200-629

MILBEHART™

(milbemycin oxime)

Flavored Tablets

INFORMATION FOR DOSING CATS

The 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: MILBEHART (milbemycin oxime) Flavored Tablets for Cats are 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% A₄ (C₃₂H₄₅NO₇, MW 555.71) and 20% A₃ (C₃₁H₄₃NO₇, MW 541.68).

Package Color	Milbemycin oxime tablet
Blue	5.75 mg
Purple	11.5 mg
Red	23.0 mg

Indications: MILBEHART™ Flavored Tablets for Cats are 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: MILBEHART™ Flavored Tablets for Cats are given orally, once a month, at the recommended minimum dosage rate of 0.9 mg milbemycin oxime per pound of body weight (2.0mg/kg).

Recommended Dosage Schedule for Cats

Body Weight	MILBEHART™ Flavored Tablets
1.5-6 lbs.	One tablet (5.75 mg)
6.1-12 lbs.	One tablet (11.5 mg)
12.1-25 lbs.	One tablet (23.0 mg)

Administration: MILBEHART™ Flavored Tablets for Cats 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.

MILBEHART™ Flavored Tablets for Cats must be administered monthly, preferably on the same date each month. The first dose should be administered within one month of the cats 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 MILBEHART™ Flavored Tablets 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 MILBEHART™ Flavored Tablets for Cats (See Precautions).

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: MILBEHART™ Flavored Tablets 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 neurotransmission.

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 10X also demonstrated no drug-related adverse effects in kittens and young adult cats.

How supplied: MILBEHART™ Flavored Tablets for Cats are 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 tablets each, which are packaged 10 per display carton.

Storage conditions: MILBEHART™ Flavored Tablets for Cats should be stored at room temperature, between 68° and 77°F (20-25°C).

Manufactured for:

Virbac AH, Inc.

P.O. Box 162059

Fort Worth, TX 76161

Phone: 1-800-338-3659

Made in Canada.

Approved by FDA under ANADA # 200-629

PRINCIPAL DISPLAY PANEL - 2.3 mg Tablet Blister Pack

MILBEHART™

(milbemycin oxime)

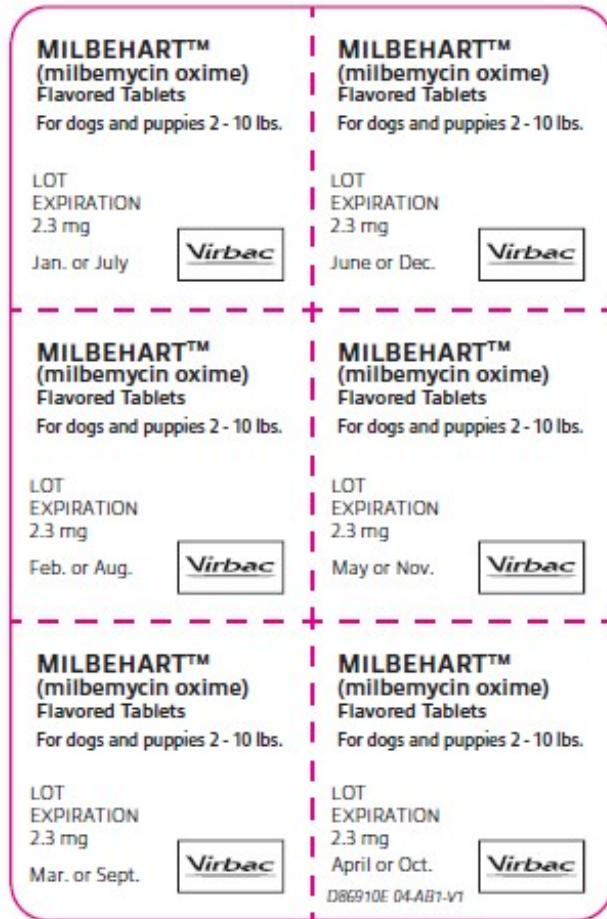
Flavored Tablets

For dogs and puppies 2-10 lbs.

LOT

EXPIRATION

2.3 mg



PRINCIPAL DISPLAY PANEL - 2.3 mg Carton

MILBEHART™

(milbemycin oxime)

Flavored Tablets

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.

For dogs 2-10 lbs.

Net contents: 6 tablets 2.3 mg each.

Approved by FDA under ANADA # 200-629

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.

Give monthly

6 pack



PRINCIPAL DISPLAY PANEL - 5.75 mg Tablet Blister Pack

MILBEHART™

(milbemycin oxime)

Flavored Tablets

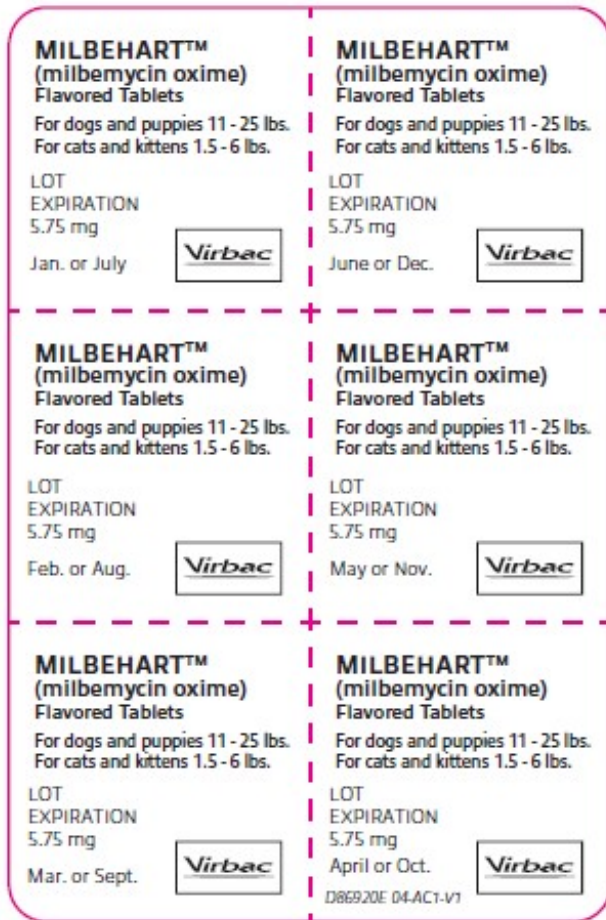
For dogs and puppies 11-25 lbs.

For cats and kittens 1.5-6 lbs.

LOT

EXPIRATION

5.75 mg



PRINCIPAL DISPLAY PANEL - 5.75 mg Carton

MILBEHART™

(milbemycin oxime)

Flavored Tablets

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.

For dogs 11-25 lbs.

For cats 1.5-6 lbs.

Net contents: 6 tablets 5.75 mg each.

Approved by FDA under ANADA # 200-629

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.

Give monthly

6 pack



PRINCIPAL DISPLAY PANEL - 11.5 mg Tablet Blister Pack

MILBEHART™

(milbemycin oxime)

Flavored Tablets

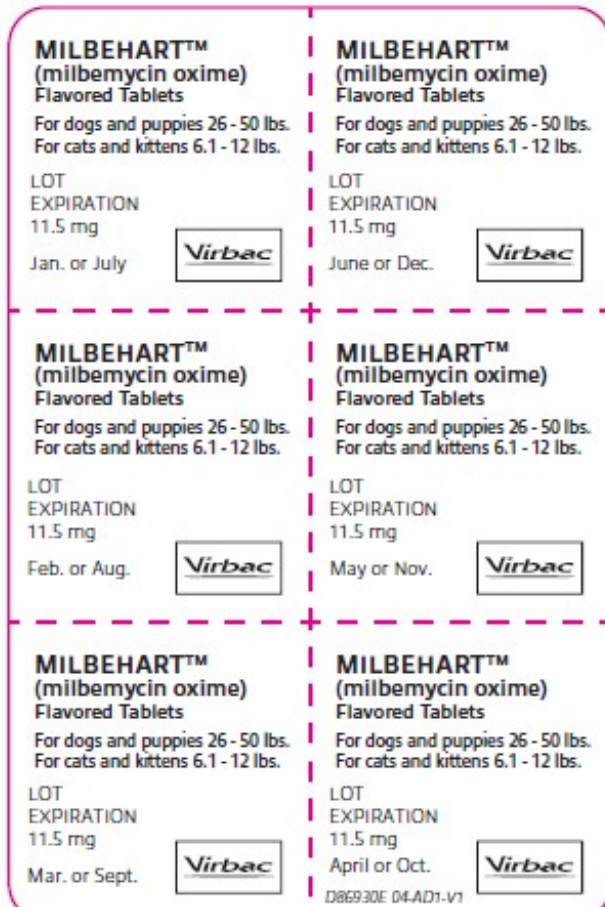
For dogs and puppies 26-50 lbs.

For cats and kittens 6.1-12 lbs.

LOT

EXPIRATION

11.5 mg



PRINCIPAL DISPLAY PANEL - 11.5 mg Carton

MILBEHART™

(milbemycin oxime)

Flavored Tablets

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.

For dogs 26-50 lbs.

For cats 6.1-12 lbs.

Net contents: 6 tablets 11.5 mg each.

Approved by FDA under ANADA # 200-629

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.

Give monthly

6 pack



PRINCIPAL DISPLAY PANEL - 23 mg Blister Pack

MILBEHART™

(milbemycin oxime)

Flavored Tablets

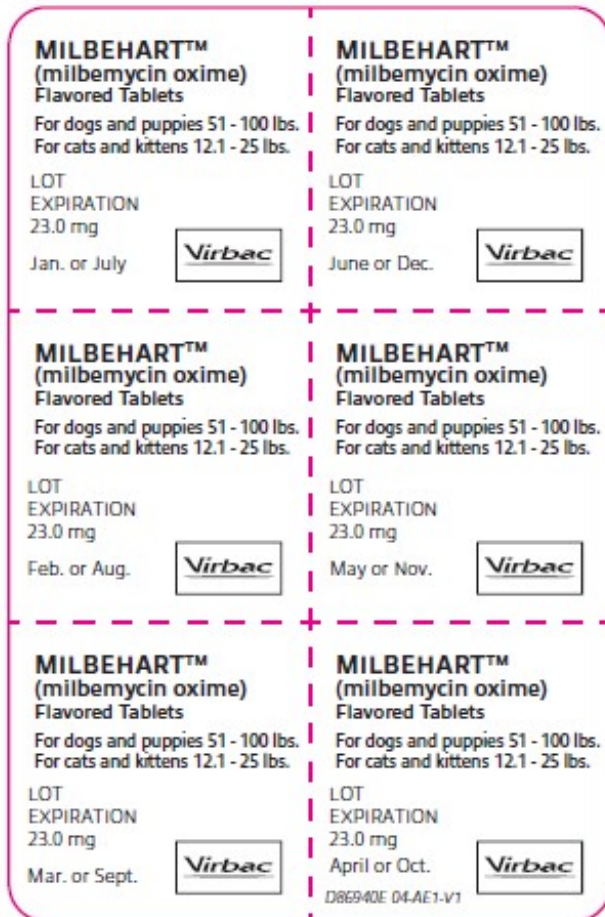
For dogs and puppies 51-100 lbs.

For cats and kittens 12.1-25 lbs.

LOT

EXPIRATION

23.0 mg



PRINCIPAL DISPLAY PANEL - 23 mg Carton

MILBEHART™

(milbemycin oxime)

Flavored Tablets

BROAD SPECTRUM PARASITICIDE

Contains once-a-month Flavored Tablets to prevent heartworm disease, control adult hookworm infestation, 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.

For dogs 51-100 lbs.

For cats 12.1-25 lbs.

Net contents: 6 tablets 23.0 mg each.

Approved by FDA under ANADA # 200-629

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.

Give monthly

6 pack



MILBEHART FLAVORED

milbemycin oxime tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-115
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

Product Characteristics

Color	brown (beige mottled)	Score	no score
Shape	ROUND	Size	6mm
Flavor	MEAT	Imprint Code	PAH;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-115-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200629	04/02/2021	

MILBEHART FLAVORED

milbemycin oxime tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-116
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

Product Characteristics

Color	brown (beige mottled)	Score	no score
Shape	ROUND	Size	8mm
Flavor	MEAT	Imprint Code	PAH;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-116-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200629	04/02/2021	

MILBEHART FLAVORED

milbemycin oxime tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-117
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

Product Characteristics

Color	brown (beige mottled)	Score	no score
Shape	ROUND	Size	10mm
Flavor	MEAT	Imprint Code	PAH;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-117-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200629	04/02/2021	

MILBEHART FLAVORED

milbemycin oxime tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:51311-118
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MILBEMYCIN OXIME (UNII: 0502PUN0GT) (MILBEMYCIN OXIME - UNII:0502PUN0GT)	MILBEMYCIN OXIME	23 mg

Product Characteristics

Color	brown (beige mottled)	Score	no score
Shape	ROUND	Size	16mm
Flavor	MEAT	Imprint Code	PAH;23
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-118-01	1 in 1 CARTON		
1		6 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200629	04/02/2021	

Labeler - Virbac AH, Inc. (131568396)**Registrant** - Ceva Sante Animale (261126049)