

MILBEMITE- milbemycin oxime solution
Elanco US Inc.

MILBEMITE™ OTIC Solution

(0.1% milbemycin oxime)

Caution: U.S. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

MILBEMITE OTIC Solution is available in plastic dispensing tubes. Each plastic tube contains 0.25 mL of MILBEMITE OTIC Solution as a 0.1% solution 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).

Indications:

MILBEMITE OTIC Solution is indicated for treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens four weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.

Human Warnings:

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

Precautions:

The safe use of MILBEMITE OTIC Solution in cats used for breeding purposes, during pregnancy, or in lactating queens, has not been evaluated.

Adverse Reactions:

No adverse reactions caused by MILBEMITE OTIC Solution have been reported in controlled effectiveness studies in adult cats and kittens (4 weeks of age).

Dosage:

MILBEMITE OTIC Solution should be administered topically into the external ear canal as the entire contents of a single-dose tube per ear. The volume delivered will be approximately 0.2 mL, with 0.05 mL residual volume remaining in dispensing tube. Repeat the treatment one time if necessary, based upon the ear mite life cycle and the response to treatment.

Administration:

MILBEMITE OTIC Solution should be administered as one tube per ear as a single treatment. Each foil pouch contains two tubes of solution, one for each ear. Open the tube by pressing cap down firmly to break seal. Remove cap and check to be sure tip of tube is open. Squeeze the tube to administer the contents of one tube into each external ear canal. Massage the base of the ear for optimal distribution. In clinical field trials, ears were not cleaned and many animals still had debris in their ears at the end of the study. Cleaning of the external ear canal prior to treatment may be performed, but is not necessary to provide effectiveness.

Effectiveness:

The clinical effectiveness of milbemycin oxime 0.1% solution was evaluated in a placebo-controlled clinical field trial of client-owned cats. *Otodectes cynotis* infestation was diagnosed by direct microscopic visualization of ear swab debris. Test or placebo treatment was administered to both ears of the cat following the pre-treatment examination. Cats' ears were examined by ear swab microscopy at multiple intervals throughout the life cycle of the mite (up to day 30). Ninety-nine percent (99%) of the milbemycin oxime-treated group were ear mite negative at the microscopic exams.

Safety:

A study was conducted using otic doses of 0.1, 0.3 or 0.5% milbemycin oxime solutions administered once weekly for six applications in kittens that were 4 weeks of age at the initiation of the study. Otic doses of 0.1 and 0.3% did not produce adverse systemic or local effects. One kitten treated with 0.5% was lethargic 8 hours after the second treatment. The kitten was offered milk replacer and by 10 hours post-treatment it appeared normal. In this kitten, lethargy was not observed after subsequent treatments. A study was conducted to evaluate the safety of a 0.1% milbemycin oxime solution in adult cats. Topical doses at 1X, 3X or 5X the recommended dose applied in one ear did not produce adverse effects.

Storage Conditions:

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

How Supplied:

MILBEMITE OTIC Solution is supplied in individual white polypropylene tubes, paired in a foil overlay pouch. The product is packaged in a box of 10 pouches of 2 tubes of 0.25 mL each.

Product of Japan

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

Approved by FDA under NADA # 141-163

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Revision Date: May 2022

PA103718X

Elanco™

Principal Display Panel - Carton Label

MilbeMite™

OTIC Solution (0.1% milbemycin oxime)

A topical medication for the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens.

**FOR USE IN CATS & KITTENS
FOUR WEEKS OF AGE AND OLDER**

Net Contents:
10 pouches of
2 tubes of
0.25 mL each



Principal Display Panel - Pouch Label

MilbeMite™

OTIC Solution (0.1% milbemycin oxime)

For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens.

FOR USE IN CATS & KITTENS FOUR WEEKS OF AGE AND OLDER

Net Contents: 2 tubes of 0.25 mL each

HUMAN WARNINGS:

Not for human use. 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.



CONTENTS: Contains MILBEMITE OTIC Solution (0.1% milbemycin oxime) to be used for treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens four weeks of age and older.

ADMINISTRATION: MILBEMITE OTIC Solution should be administered as one tube per ear as a single treatment. Cleaning of the external ear canal prior to treatment may be performed, but is not necessary to provide effectiveness. (See insert for details.)

STORAGE CONDITIONS: MILBEMITE OTIC Solution should be stored at room temperature, between 59° and 77°F (15-25°C).

Product of Japan

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

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Elanco

Text Read Direction - Back Side

MILBEMITE

milbemycin oxime solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58198-8602
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Milbemycin oxime (UNII: 0502PUN0GT) (Milbemycin oxime - UNII:0502PUN0GT)	Milbemycin oxime	1 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-8602-5	10 in 1 BOX		
1		2 in 1 POUCH		
1		0.25 mL in 1 TUBE		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
NADA	NADA141163	11/01/2015	

Labeler - Elanco US Inc. (966985624)

Establishment

Name	Address	ID/FEI	Business Operations
Accupac, LLC		061595175	MANUFACTURE, PACK, LABEL

Establishment

Name	Address	ID/FEI	Business Operations
Packaging Coordinators, LLC		078525133	PACK, LABEL

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Livzon Group Fuzhou Fuxing Pharmaceutical Co., Ltd.		421260459	API MANUFACTURE

Revised: 11/2022

Elanco US Inc.