

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-didehydro- milbemycins 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.
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