

BLUE RIDGE PHARMACEUTICALS, INC.

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The following information is from the most recent U.S.A. product label/insert supplied to us by the Manufacturer/Distributor.

ACAREXX™

Rx

Blue Ridge

Otic Parasiticide

(0.01% Ivermectin) Otic Suspension

NADA No.: 141-174

Active Ingredient(s): Each ampule is filled to deliver 0.5 mL of 0.01% ivermectin otic suspension per ear.

Indications: ACAREXX™ (ivermectin) is indicated for the treatment of adult ear mite (*Otodectes cynotis*) infestations in cats and kittens four weeks of age or older. Effectiveness against eggs and immature stages has not been proven.

Pharmacology: Description: Chemical Name: Ivermectin is a mixture of 5-0-demethyl-22, 23-dihydroavermectin A_{1a} (component B_{1a}) and 5-0-demethyl-25-de (1-methylpropyl)-22, 23-dihydro-25-(1-methylethyl)avermectin A_{1b} (component B_{1b}).

Empirical formula: B_{1a} = C₄₈H₇₄O₁₄, B_{1b} = C₄₇H₇₂O₁₄. Molecular weight: B_{1a} = 875.10, B_{1b} = 861.07

Dosage and Administration: Dosage: ACAREXX™ is administered topically in the ear canal at an ivermectin concentration of 0.01%. One dose of 0.5 mL is applied in each ear. Repeat treatment one time if necessary, based upon the ear mite life cycle and the response to treatment.

Administration: Tear foil pouch at the notch to remove the two plastic ampules. Use one ampule per ear. Shake well before use. Snap off the cap of the ampule and place the tip into the external ear canal. Squeeze the entire contents of one ampule into the ear and massage the base of the ear to distribute the medication. Repeat the procedure in the other ear using the second ampule. In clinical field trials, ears were not cleaned and many animals still had debris in their ears at the end of the study. Cleaning the ears prior to administration of ACAREXX™ is not necessary to provide effectiveness.

Precaution(s): Storage Conditions: ACAREXX™ should be stored at temperatures below 86°F (30°C). Protect from freezing.

Caution(s): U.S. Federal Law restricts this drug to use by or on the order of a licensed

veterinarian.

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

Warning(s): Human Warnings: Not for human use. Keep out of reach of children.

Adverse Reactions: In approximately 1% of 80 cats and kittens, pain associated with the pinna and vomiting were observed following treatment with ACAREXX™.

For technical assistance or to report adverse drug reactions, please call 1-800-374-8006.

Trial Data: Effectiveness: One treatment with ACAREXX™ was 92% effective in treating adult ear mite (*Otodectes cynotis*) infestations after 7 days in a dose titration/confirmation study. In a well-controlled clinical field trial, one treatment of ACAREXX™ was 94% effective in clearing cats and kittens of adult ear mite infestations within 7 to 10 days.

Safety: In two Target Animal Safety studies, ACAREXX™ was proven to be safe in kittens four weeks of age or older. Four week old kittens were administered ACAREXX™ at dose rates of 1X, 3X, and 5X the recommended dose for three or six consecutive days and no adverse reactions were observed except one kitten treated at 1X the dose had histologic evidence of minimal, chronic dermal inflammation of the ear. In a well-controlled clinical field trial, ACAREXX™ was used safely in cats and kittens receiving other frequently used veterinary products such as flea control products, vaccines, anthelmintics, antibiotics, and steroids.

Presentation: ACAREXX™ is packaged in two polypropylene ampules per foil pouch, which are packaged 12 foil pouches per display carton.

ACAREXX is a trademark of Blue Ridge Pharmaceuticals, Inc.

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Disclaimer: Every effort has been made to ensure the accuracy of the information published. However, it remains the responsibility of the readers to familiarize themselves with the product information contained on the product label or package insert. Compendium Code No.: 15070020