# KC OTO-PACK- hydrocortisone, ketoconazole gel DermaZoo, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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## INDICATIONS AND USAGE

PRE-USE: Prior to applying KC Oto-Pack<sup>TM</sup>, after examining the dog or cat, and preferably doing cytology, clean and dry the ear canal using GlycoZoo<sup>TM</sup> Otic.

DIRECTIONS: Shake or stir well, then draw 2-5 mL or more of KC Oto-Pack, depending upon size of pet, into a clean (feeding) syringe. Insert tip of syringe into ear canal and apply product by pushing the plunger. KC Oto-Pack will begin to thicken as it warms to the pet's body temperature. Rub ears and prevent head shaking for about a minute to allow product to settle into ear canal and totally thicken. Take precautions to avoid introduction of contaminants.

KC Oto-Pack aids in the treatment of otitis externa and ear itching due to yeast infections, and does not need to be removed. Reapply as needed every 7 days.

### WARNINGS AND PRECAUTIONS

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Avoid contact with eyes. For dog and cat topical use only. Keep out of reach of children. See insert for more information.

## **DESCRIPTION**

ACTIVE INGREDIENTS: 1.0% Hydrocortisone, 0.15% Ketoconazole

INACTIVE INGREDIENTS: Water, Poloxamer 407, Propylene Glycol, Gycolic Acid, Iodopropynyl Butylcarbamate

# STORAGE CONDITIONS

STORE THIS SIDE UP

STORE AT ROOM TEMPERATURE

After opening container, discard contents after 90 days.

# KC Oto-Pack<sup>TM</sup>

THERMALLY ACTIVATED GEL

Hydrocortisone

Ketoconazole

FOR DOGS & CATS

Net Contents: 2 oz. (54 ml)

Made in USA

Manufactured for: DermaZoo™ Pharma, www.dermazoo.com, info@dermazoo.com

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MADE IN USA

DERMAZOO'

KC Oto-Pack<sup>™</sup>

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Store at room temperature. After opening container, discard contents after 90 days.

# KC OTO-PACK

FOR DOGS

hydrocortisone, ketoconazole gel

## **Product Information**

Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:86002-103

Route of Administration AURICULAR (OTIC)

# **Active Ingredient/Active Moietv**

| 6  |                          |                   |  |  |  |  |
|--|--------------------------|-------------------|--|--|--|--|
| Ingredient Name  | <b>Basis of Strength</b> | Strength          |  |  |  |  |
| <b>HYDRO CORTISONE</b> (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ) | HYDROCORTISONE           | 1 g in 1000 mL    |  |  |  |  |
| KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)               | KETOCONAZOLE             | 0.15 g in 1000 mL |  |  |  |  |

# **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0KO0R) POLOXAMER 407 (UNII: TUF2IVW3M2) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) GLYCOLIC ACID (UNII: 0WT12SX38S) IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)

| Packaging |                  |                      |                             |                    |  |  |  |
|-----------|------------------|----------------------|-----------------------------|--------------------|--|--|--|
| #         | Item Code        | Package Description  | <b>Marketing Start Date</b> | Marketing End Date |  |  |  |
| 1         | NDC:86002-103-02 | 54 mL in 1 CONTAINER |                             |                    |  |  |  |

| <b>Marketing Infor</b> | arketing Information                     |                      |                    |  |  |  |
|------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |  |
| unapproved drug other  |  | 03/20/2015           |                    |  |  |  |

# Labeler - DermaZoo, LLC (969506752)

Revised: 3/2015 DermaZoo, LLC