# FORTICEPT ANTISEPTIC EAR FLUSH- ketoconazole liquid Lidan, Inc.

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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## Forticept Antiseptic Ear Flush - Medicated Otic Cleanser

### **Active Ingredient(s):**

Ketoconazole......0.2% (Antifungal)

#### Indications:

Medicated cleansing and flushing solution to support topical conditions responsive to Ketoconazole.

## Warnings:

For external use only / Not for human use
Keep out of reach of children
When using this product - Avoid contact with eyes and mucous membranes.
Stop use and ask a veterinarian if condition worsens, or irritation occurs.

#### **Directions:**

**For use on ears:** apply solution to the ear canal and with firm but gentle pressure, massage the base of the ear.

Use an absorbent material to clean any excess solution and wipe away debris. Do not allow the animal to lick the

treated area until dry to prevent ingestion. Wash hands after use.

## Storage:

Store at room temperature - 68F to 77F (20°C-25°C) Protect from freezing or excessive heat

#### First Aid:

If eye contact occurs or skin irritation develops, rinse thoroughly with water, discontinue use, and if irritation persists, contact a veterinarian.

If large quantities of this material are swallowed, contact poison control center immediately!

## Inactive ingredients:

Water, Polysorbate 20, Propylene Glycol, Aloe Barbadensis Leaf Juice, Ethoxydiglycol, Glycerin, Lactic Acid, Benzyl Alcohol, Boric Acid, Calendula Officinalis, Fragrance

#### 8 fl. oz. Label



#### FORTICEPT ANTISEPTIC EAR FLUSH

For Dogs & Cats

8 fl. oz. (237mL)

ketoconazole liquid

| Product Information     |                 |                    |                |  |
|-------------------------|-----------------|--------------------|----------------|--|
| Product Type            | OTC ANIMAL DRUG | Item Code (Source) | NDC:72127-0904 |  |
| Route of Administration | TOPICAL         |                    |                |  |

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| Active Ingredient/Active Moiety                                  |                          |               |
|--|--------------------------|---------------|
| Ingredient Name  | <b>Basis of Strength</b> | Strength      |
| KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I) | KETOCONAZOLE             | 2 g in 1000 g |
|  |                          |               |

| Inactive Ingredients                                 |          |  |  |
|--|----------|--|--|
| Ingredient Name                                      | Strength |  |  |
| WATER (UNII: 059QF0KO0R)                             |          |  |  |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)                    |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                  |          |  |  |
| ALOE VERA LEAF (UNII: ZY81Z83H0X)                    |          |  |  |
| DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B) |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                          |          |  |  |
| LACTIC ACID (UNII: 33X04XA5AT)                       |          |  |  |
| BENZYL ALCOHOL (UNII: LKG8494WBH)                    |          |  |  |
| BORIC ACID (UNII: R57ZHV85D4)                        |          |  |  |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)      |          |  |  |

| Packaging |                  |                               |                             |                           |
|-----------|------------------|-------------------------------|-----------------------------|---------------------------|
| #         | Item Code        | Package Description           | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1         | NDC:72127-0904-1 | 237 g in 1 BOTTLE, DISPENSING |                             |                           |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| unapproved drug other |   | 08/18/2022              |                       |
| 00                    |   |                         |                       |

## **Labeler -** Lidan, Inc. (014456716)

## Registrant - Lidan, Inc. (014456716)

| Establishment             |         |           |  |  |
|---------------------------|---------|-----------|--|--|
| Name                      | Address | ID/FEI    | Business Operations                          |  |
| Cosco International, Inc. |         | 016433141 | manufacture, api manufacture, analysis, pack |  |

Revised: 8/2022 Lidan, Inc.