# **HEALTHMART EARWAX REMOVAL KIT EAR WAX DROPS AND BULB- carbamide peroxide**

McKesson Corp via Strategic Sourcing Services LLC

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## HealthMart Earwax Removal Kit, Ear wax drops & Bulb

#### **Drug Facts**

#### Active ingredient

Carbamide peroxide 6.5%

#### **Purpose**

Ear wax removal aid

#### Uses

for occasional use as an aid to soften, loosen, and remove excessive ear wax

#### Warnings

#### For use in the ear only

# Ask a doctor before use if you have

• ear drainage or discharge • ear pain • irritation, or rash in the ear • dizziness • an injury or perforation (hole) of the ear drum • recently had ear surgery

# When using this product

• avoid contact with the eyes

# Stop use and ask a doctor if

• you need to use for more than 4 days • excessive ear wax remains after use of this product

# Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center (800-222-1222) right away.

#### **Directions**

# FOR USE IN THE EAR ONLYAdults and children over 12 years of age:

consult a doctor Children under 12 years:

Tilt head sideways and place 5 to 10 drops into ear

- Tip of applicator should not enter ear canal
- Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear
- Use twice daily for up to 4 days if needed, or as directed by a doctor
- Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe

#### Other information

- Avoid exposing bottle to excessive heat and direct sunlight
- Store bottle in the outer carton
- Keep cap on bottle when not in use
- Product foams on contact with ear wax due to release of oxygen. There may be an associated crackling sound
- Do not use if tamper-evident safety seal is broken or missing

#### Inactive ingredients

anhydrous citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, water

Questions?

1-800-328-5890

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#### Other information

- Avoid exposing bottle to excessive heat and direct sunlight
- Store bottle in the outer carton
- Do not store above 25°C (77°F)
- Keep cap on bottle when not in use
- Product foams on contact with ear wax due to release of oxygen. There may be an associated crackling sound.
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# Questions?

Weekdays 8:30-5:00 CST **1-800-328-5890** 

# Package Labeling:Kit



Package Labeling:62011-0483-1



Non-Irritating

elineb.

• Sate

Carbamide Peroxid e 6.5%

#### Earwax Removal Aid

# **Drug Facts** (continued)

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- Product foams on contact with ear wax due to release of oxygen. There may be an associated crackling sound.
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# **Questions?** 1-800-328-5890

**1-800-328-5890** Weekdays 8:30-5:00 CST

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#### **REV 11/21**

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Compare to Debrox® active ingredient\*

# Earwax Removal Drops

Carbamide Peroxide 6.5%

Earwax Removal Aid

> Safe, Gentle, Non-Irritating

0.5 FJ Oz (15 mL)

Earwax Removal

Drop



LOT & EXP AREA.

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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Earwax Removal
Carbamide Peroxide 6.5%

Non-Irritating

# HEALTHMART EARWAX REMOVAL KIT EAR WAX DROPS AND BULB

carbamide peroxide kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62011-0484

#### **Packaging**

# Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:62011-0484-1 1 in 1 KIT 02/25/2022

| O | uantity  | of | <b>Parts</b> |
|---|----------|----|--------------|
| Y | MALILILY | •  | i aits       |

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
|        |                  |                        |

Part 1 1 BOTTLE 15 mL

# Part 1 of 1

# **HEALTHMART EAR WAX REMOVAL DROPS**

carbamide peroxide solution/ drops

# **Product Information**

Item Code (Source) NDC:62011-0483

Route of Administration TOPICAL

| Active Ingredient/Active Moiety         |                       |                  |  |
|-----------------------------------------|-----------------------|------------------|--|
| Ingredient Name                         | Basis of<br>Strength  | Strength         |  |
| (0.111111111111111111111111111111111111 | CARBAMIDE<br>PEROXIDE | 65 mg<br>in 1 mL |  |

| Inactive Ingredients                     |          |  |  |
|------------------------------------------|----------|--|--|
| Ingredient Name                          | Strength |  |  |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)              |          |  |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)      |          |  |  |
| SODIUM CITRATE (UNII: 1Q73Q2JULR)        |          |  |  |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) |          |  |  |
| WATER (UNII: 059QF0KO0R)                 |          |  |  |

| I | Packaging            |                                                      |                         |                       |  |
|---|----------------------|------------------------------------------------------|-------------------------|-----------------------|--|
| 4 | tem Code             | Package Description                                  | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:62011-<br>0483-1 | 1 in 1 BOX                                           |                         |                       |  |
| : |                      | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product |                         |                       |  |

| Marketing Information |                                             |                         |                       |  |
|-----------------------|---------------------------------------------|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M014                                        | 02/25/2022              |                       |  |

| Marketing Information |                                             |                         |                       |  |
|-----------------------|---------------------------------------------|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M014                                        | 02/25/2022              |                       |  |
|                       |                                             |                         |                       |  |

# **Labeler -** McKesson Corp via Strategic Sourcing Services LLC (116956644)

| Establishment              |         |           |                            |  |
|----------------------------|---------|-----------|----------------------------|--|
| Name                       | Address | ID/FEI    | <b>Business Operations</b> |  |
| Bell Pharmaceuticals, Inc. |         | 140653770 | manufacture(62011-0484)    |  |

Revised: 12/2023 McKesson Corp via Strategic Sourcing Services LLC