

TOPCARE EARWAX REMOVAL KIT- carbamide peroxide liquid
TOPCO ASSOCIATES LLC

TopCare Earwax Removal Kit

Drug facts

Active ingredient

Carbamide peroxide 6.5%

Purpose

Earwax removal aid

Uses

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

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 earwax remains after use of this product

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Directions

FOR USE IN THE EAR ONLY

Adults and children over 12 years of age:

- 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 titled 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

Children under 12 years: consult a doctor

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 earwax 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

*This product is not manufactured or distributed by Prestige Brands Inc. owner of the registered trademark Debrox.

Distributed By Topco Associates LLC ELK Frove Village, IL 60007 Topco BPH414
Questions? 1-888-423-0139 topcare@topco.com

Product Label

TopCare health

Earwax Removal Kit

CARBAMIDE PEROXIDE 6.5%

- Ear Wax Removal Aid
- Safe
- Gentle
- Non-irritating

QUALITY GUARANTEED
This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



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0.5 FL OZ (15mL)

NDC:36800-835-33

TopCare health

COMPARE TO DEBROX® ACTIVE INGREDIENT*

Earwax Removal Kit

CARBAMIDE PEROXIDE 6.5%

- Ear Wax Removal Aid
- Safe
- Gentle
- Non-irritating



WASHER BULB & DROPS INCLUDED

OUR PHARMACIES RECOMMEND

0.5 FL OZ (15mL)

TopCare health

COMPARE TO DEBROX® ACTIVE INGREDIENT*

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Earwax Removal Kit

TopCare health

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

| Drug Facts | |
|--|--------------------------------------|
| Active ingredient Carbamide peroxide 6.5% | Purpose Earwax removal aid |
| Uses for occasional use as an aid to soften, loosen, and remove excessive earwax | |
| Warnings For use in the ear only Ask a doctor before use if you have: <input type="checkbox"/> ear drainage or discharge <input type="checkbox"/> ear pain <input type="checkbox"/> irritation, or rash in the ear <input type="checkbox"/> dizziness <input type="checkbox"/> an injury or perforation (hole) of the ear drum <input type="checkbox"/> recently had ear surgery <input type="checkbox"/> When using this product avoid contact with the eyes Stop use and ask a doctor if: <input type="checkbox"/> you need to use for more than 4 days <input type="checkbox"/> excessive earwax remains after use of this product Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away. | |
| Directions FOR USE IN THE EAR ONLY Adults and children over 12 years of age: <input type="checkbox"/> Tilt head sideways and place 5 to 10 drops into ear <input type="checkbox"/> Tip of applicator should not enter ear canal <input type="checkbox"/> Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear <input type="checkbox"/> Use twice daily for up to 4 days if needed, or as directed by a doctor <input type="checkbox"/> Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe Children under 12 years: consult a doctor | |
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| Inactive ingredients <input type="checkbox"/> anhydrous citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, water | |
| Questions? 1-800-328-5890 | |

Scan here for more information



Rev 08/19

*This product is not manufactured or distributed by Fresenius Brands Inc. owner of the registered trademark Debrox®.
 TOPCO BPH40919 QUESTIONS? 1-888-423-0139
 ELK GROVE VILLAGE, IL 60007
 TOPCARE@TOPCO.COM WWW.TOPCAREBRAND.COM
 DISTRIBUTED BY TOPCO ASSOCIATES LLC

TOPCARE EARWAX REMOVAL KIT

carbamide peroxide liquid

Product Information

| | | | |
|--------------------------------|------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-835 |
| Route of Administration | AURICULAR (OTIC) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------|---------------|
| CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V) | CARBAMIDE PEROXIDE | 65 mg 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)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:36800-835-33 | 1 in 1 CARTON | 11/28/2014 | |
| 1 | | 15 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M014 | 11/28/2014 | |

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------------|---------|-----------|------------------------|
| Bell Pharmaceuticals, Inc. | | 140653770 | manufacture(36800-835) |

Revised: 12/2023

TOPCO ASSOCIATES LLC