

LUCID HEARING EARWAX REMOVAL KIT AND BULB- carbamide peroxide
Hearing Lab Technology LLC

Lucid Hearing Earwax Removal Kit & Bulb

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 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 sort 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
- Store at 15-30°C (59-86°F)
- 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

Package Labeling:



Products Not Shown at Actual Size



NDC XXXXX-XXX-XX

Earwax Removal Kit

Compare to Debrox® active ingredient*

Carbamide Peroxide 6.5% Earwax Removal Aid


Safe • Gentle • Non-irritating

0.5 FL OZ (15 mL)

IN THE BOX

- 1 Bottle Earwax Removal Drops
- Washer Bulb

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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	
<ul style="list-style-type: none"> ■ 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	
<ul style="list-style-type: none"> ■ 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	
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<ul style="list-style-type: none"> ■ Avoid exposing bottle to excessive heat and direct sunlight ■ Store bottle in the outer carton ■ Use 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	
<ul style="list-style-type: none"> ■ 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:
Lucid Hearing Holding Company, LLC,
PO BOX 535596, Grand Prairie, TX 75053 LBL-0326 Rev05



Earwax Removal Drops

Carbamide Peroxide 6.5% Earwax Removal Aid

0.5 FL OZ (15 mL)

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Drug Facts	Active ingredient Purpose Carbamide peroxide 6.5%..... Earwax removal aid	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 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 Children under 12 years: consult a doctor
Inactive ingredients anhydrous citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, water		Questions? 1-800-328-5890

LOT:
EXP:

LBL-0325 Rev01

LUCID HEARING EARWAX REMOVAL KIT AND BULB

carbamide peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84320-001
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84320-001-00	1 in 1 BOX	05/11/2024	
1		1 in 1 KIT; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	15 mL

Part 1 of 1

LUCID HEARING EARWAX REMOVAL DROPS

carbamide peroxide solution/ drops

Product Information

Item Code (Source)	NDC:84320-002
Route of Administration	TOPICAL

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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:84320-002-00	15 mL in 1 BOTTLE; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	05/11/2024	

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OTC Monograph Drug	M014	05/11/2024	

Labeler - Hearing Lab Technology LLC (827693503)

Revised: 5/2024

Hearing Lab Technology LLC