

HAL-HEN EARWAX REMOVAL SYSTEM- carbamide peroxide
Warner Tech-care Products, LLC

Hal-Hen Earwax Removal System

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

Adult 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

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 cracking 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?

1-800-242-5436

Package Labeling: Kit

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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Hearing Healthcare

Earwax Removal System



Hearing Healthcare

Earwax Removal System



Earwax Removal Aid



Hearing Healthcare

Earwax Removal System



Earwax Removal Aid

Compare to Debrox® active ingredient*



Hearing Healthcare

Earwax Removal System



Earwax Removal Aid

Safe, Gentle, Non-Irritating



8 10260 02006 5

Washer Bulb Included

Carbamide Peroxide 6.5%
0.5 Fl Oz (15 mL)

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*This product is not manufactured or distributed by Prestige Brands Inc. owner of the registered trademark Debrox®.
Manufactured for: Hal-Hen Company, Inc.
Garden City Park, NY 11040 • Made in U.S.A.

REV 02/14

Package Labeling:



Hearing Healthcare

Earwax Removal Aid Drops

Earwax Removal Aid



Compare to Debrox® active ingredient*

Safe, Gentle, Non-Irritating

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0.5 Fl Oz (15 mL)

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Drug Facts (continued)

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REV 02/14



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Garden City Park, NY 11040 • Made in U.S.A.

HAL-HEN EARWAX REMOVAL SYSTEM

carbamide peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69428-004
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69428-004-00	1 in 1 KIT	06/01/2014	

Quantity of Parts

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

Part 1 of 1

HAL HEN EARWAX REMOVAL AID DROPS

carbamide peroxide solution/ drops

Product Information

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:69428-001-00	1 in 1 BOX		
1		15 mL in 1 BOTTLE; 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	05/01/2014	

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Labeler - Warner Tech-care Products, LLC (080326764)

Revised: 1/2024

Warner Tech-care Products, LLC