

**HAL HEN EARWAX REMOVAL AID DROPS- carbamide peroxide solution/ drops
Warner Tech-care Products, LLC**

Hal Hen Earwax Removal Aid Drops

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:



Hearing Healthcare

Earwax Removal Aid Drops

Earwax Removal Aid



Compare to Debrox® active ingredient*

Safe, Gentle, Non-Irritating

Carbamide Peroxide 6.5%
0.5 Fl Oz (15 mL)

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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Drug Facts (continued)

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REV 02/14



*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.

HAL HEN EARWAX REMOVAL AID DROPS

carbamide peroxide solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69428-001
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

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

UNII:BBX060AN9V)

PEROXIDE

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: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69428-001-00	1 in 1 BOX	05/01/2014	
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	

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

Name	Address	ID/FEI	Business Operations
Bell Pharmaceuticals, Inc.		140653770	manufacture(69428-001)

Revised: 12/2023

Warner Tech-care Products, LLC