

**EAR WAX REMOVAL AID DROPS- carbamide peroxide liquid  
PHARMACY VALUE ALLIANCE, LLC**

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**Premier Value Ear Wax Removal Aid Drops**

***Active ingredient***

Carbamide Peroxide 6.5%

***Purpose***

Earwax removal aid

***Uses***

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

***Warnings***

**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 eardrum
- 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 four days
- excessive ear wax remains after use this product

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away at (1-800-222-1222).

***Directions***

**FOR USE IN THE EAR ONLY.**

- **Adults and children over 12 years of age:**

- tilt head sideways
- place 5 to 10 drops into ear canal.
- 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 four 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 of age:** consult a doctor.

### ***Other information***

- Store at room temperature
- Avoid exposing bottle to excessive heat and direct sunlight
- Store bottle in the outer carton
- Product foams on contact with earwax due to release of oxygen. There may be an associated “cracking” sound.
- Keep cap on bottle when not in use

### ***Inactive ingredients***

adipic acid, anhydrous glycerin, polysorbate 80.

### ***Questions or comments?***

**1-866-467-2748**

## **PRINCIPAL DISPLAY PANEL**

Premier Value®

NDC 68016-793-15

\*COMPARE TO THE ACTIVE INGREDIENT IN DEBROX® DROPS

EAR WAX REMOVAL AID DROPS KIT

Carbamide Peroxide 6.5%

Ear Wax Removal Aid

- Safe & Gentle
- Microfoam Cleansing Action
- Easy to use Instructions

NET WT 0.5 FL OZ (15 mL)

This kit include soft rubber bulb ear syringe and drops

**TAMPER EVIDENT: DO NOT USE IF OUTER CARTON IS OPEN OR TORN**

**IMPORTANT: Keep the carton for future reference on full labeling.**

**Distributed BY:**

**Pharmacy Value Alliance, LLC**

**407 East Lancaster Avenue,**

**Wayne, PA 19087**

\*This product is not manufactured or distributed by Medtech Products Inc. the distributor of Debrox® Drops.



## EAR WAX REMOVAL AID DROPS

carbamide peroxide liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-793
<b>Route of Administration</b>	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CARBAMIDE PEROXIDE</b> (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	0.065 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ADIPIC ACID</b> (UNII: 76A0JE0FKJ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-793-15	1 in 1 CARTON	04/18/2019	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	04/18/2019	

**Labeler** - PHARMACY VALUE ALLIANCE, LLC (101668460)

Revised: 11/2023

PHARMACY VALUE ALLIANCE, LLC