

**DEBROX- carbamide peroxide liquid**  
**Proficient Rx LP**

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**Debrox Earwax Removal Aid**

***Drug Facts***

***Active ingredient***

Carbamide peroxide 6.5% non USP\*

\*pH differs from USP specifications

***Purpose***

Earwax removal aid

***Uses***

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

***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 earwax remains after use of this product

**Keep this and all drugs out of the reach of children.**

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

***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
- 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:** consult a doctor

### **Other information**

- do not store above 25C (77F)
- store bottle in the outer carton
- product foams on contact with earwax due to release of oxygen. There may be an associated “crackling” sound.
- keep tip on bottle when not in use

### **Inactive ingredients**

citric acid, flavor, glycerin, propylene glycol, sodium lauroyl sarcosinate, water

### **Questions or comments?**

call toll-free **1-866-255-5202** [Debrox.com](http://Debrox.com)

### **PRINCIPAL DISPLAY PANEL**

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

Debrox® DROPS

Carbamide Peroxide 6.5% Non USP\*

Earwax Removal Aid

Kit includes soft rubber bulb ear syringe and drops

½ FL OZ (15mL)



Scan Here



NDC 71205-136-15

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320



# Earwax Removal Aid (Debrox) 6.5%

## 0.5 FL OZ (15mL) Solution

Each bottle contains: Carbamide peroxide 6.5%  
non USP Earwax removal aid

See Box

Product ID: SE013615

Dist. By: Medtech Products Inc. Tarrytown, NY 10591

Do not store above 25°C (77°F)

Keep medication out of the reach of children

Earwax Removal Aid (Debrox) 6.5%  
0.5 FL OZ (15mL) Solution  
Lot #:00000 SN# MASTER  
NDC 71205-136-15 Exp:00/00/00

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NDC 71205-136-15 Exp:00/00/00



GTIN: 00371205136154  
SN# MASTER  
Exp. 00/00/00  
Lot #:00000

### DEBROX

carbamide peroxide liquid

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71205-136(NDC:63029-322)
<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	65 mg in 1 mL

#### Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>WATER</b> (UNII: 059QF0KO0R)	

#### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-136-15	1 in 1 CARTON	10/01/2018	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a		

Combination Product			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	06/01/2012	

**Labeler** - Proficient Rx LP (079196022)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-136)

Revised: 1/2024

Proficient Rx LP