

DEBROX- carbamide peroxide liquid
Proficient Rx LP

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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

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)



NDC 71205-136-15

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 Ren
0.5 FL OZ (1
Lot #:00000
NDC 71205-1

Earwax Ren
0.5 FL OZ (1
Lot #:00000
NDC 71205-1

Earwax Ren
0.5 FL OZ (1
Lot #:00000
NDC 71205-1

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DEBROX

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71205-136(NDC:63029-322)
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
WATER (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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	06/01/2012	

Labeler - Proficient Rx LP (079196022)

Establishment

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

Revised: 10/2019

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