

**DEBROX- carbamide peroxide liquid**  
**Medtech Products Inc.**

*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.*

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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**

Debrox® DROPS

Carbamide Peroxide 6.5% Non USP\*

Earwax Removal Aid

Kit includes soft rubber bulb ear syringe and drops

½ FL OZ (15mL)



## DEBROX

carbamide peroxide liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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: 059QF0K00R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-322-02	1 in 1 CARTON	06/01/2012	02/01/2018
1		7 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:63029-322-01	1 in 1 CARTON	06/01/2012	
2		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** - Medtech Products Inc. (122715688)

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Medtech Products Inc.