

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

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**DEBROX 63029-321-01**

**Debrox Earwax Removal Aid**

**Drug Facts**

**Active ingredient**

Carbamide peroxide 6.5% non USP

**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 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, in an upright position
- 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?**

1-866-255-5202 [Debrox.com](http://Debrox.com)

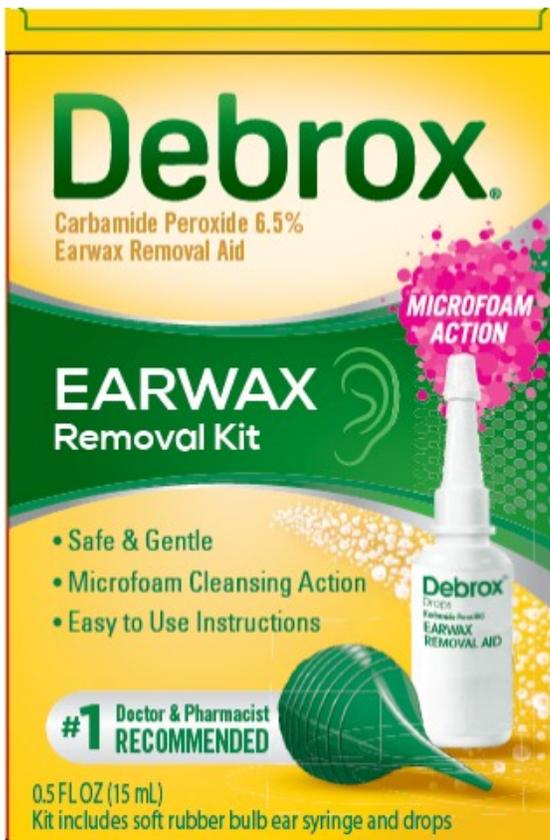
**Principal Display Panel**

**Debrox Earwax Removal Aid 0.5 FL OZ (15 mL)**



**Principal Display Panel**

**Debrox Earwax Removal Kit 0.5 FL OZ (15 mL)**



<b>DEBROX</b>				
carbamide peroxide liquid				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63029-321	
<b>Route of Administration</b>	AURICULAR (OTIC)			
<b>Active Ingredient/Active Moiety</b>				
Ingredient Name		Basis of Strength	Strength	
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		CARBAMIDE PEROXIDE	65 mg in 1 mL	
<b>Inactive Ingredients</b>				
Ingredient Name			Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)				
WATER (UNII: 059QF0KO0R)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-321-01	1 in 1 CARTON	08/01/2012	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

2	NDC:63029-321-02	1 in 1 CARTON	08/01/2012	
2		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M014		08/01/2012	

**Labeler** - Medtech Products Inc. (122715688)

Revised: 1/2025

Medtech Products Inc.