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.

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 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?

1-866-255-5202 Debrox.com

Debrox Earwax Removal Aid 0.5 FL OZ (15 mL)

DEBROX

carbamide peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63029-321
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	0.065 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:63029-321-01	1 in 1 CARTON	08/01/2012	
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	08/01/2012	

Labeler - Medtech Products Inc. (122715688)

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