

**DEBROX- carbamide peroxide liquid  
A-S Medication Solutions**

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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

**HOW SUPPLIED**

Product: 50090-4201

NDC: 50090-4201-0 15 mL in a BOTTLE, DROPPER / 1 in a CARTON

**Carbamide Peroxide**



**DEBROX**

carbamide peroxide liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50090-4201(NDC:63029-321)
<b>Route of Administration</b>	AURICULAR (OTIC)		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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</b> (UNII: 2968PHW8QP)	
<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>AQUA</b> (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4201-0	1 in 1 CARTON	03/19/2019	
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 Drug	M014	08/01/2012	

**Labeler** - A-S Medication Solutions (830016429)**Establishment**

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4201)

Revised: 9/2025

A-S Medication Solutions