

DEBROX- carbamide peroxide liquid
A-S Medication Solutions

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?

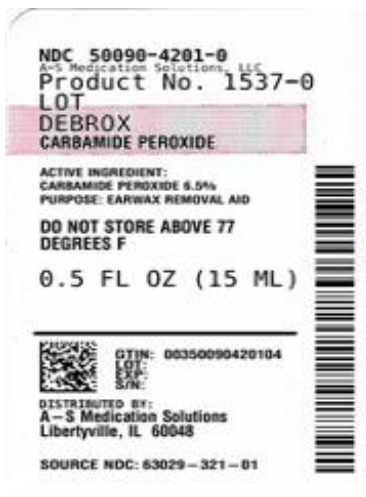
1-866-255-5202 Debrox.com

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4201(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: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: 12/2023

A-S Medication Solutions