

LEADER EARWAX REMOVAL KIT- carbamide peroxide 6.50% kit liquid
Cardinal Health, 110 dba Leader

LEADER Earwax Removal Kit

Carbamide Peroxide 6.5% non USP*

*pH differs from USP specifications

Earwax removal aid

For occasional use as an aid to soften, loosen, and remove excessive earwax.

Ask a doctor before use if you have:

ear drainage or discharge

ear pain, irritation, or rash in ear

recently had ear surgery

dizziness

an injury or perforation of the eardrum

Citric acid

Flavor

Glycerin

Propylene glycol

Sodium Lauroyl Sarcosinate

Sodium Stannate

Purified water

- 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 ear with warm water, using a soft rubber bulb ear syringe

If swallowed, get medical help or contact a Poison Control Center right away.

LEADER²TM

NDC 70000-0490-1

Earwax Removal Drops

Carbamide Peroxide, 6.5%
Earwax Removal Aid

Safe & Gentle
Foaming Cleansing
Action

0.5 FL OZ (15 mL)

DO NOT USE IF SHRINKBAND ON BOTTLE IS BROKEN OR MISSING.

Drug Facts	Purpose
Active Ingredient Carbamide peroxide 6.5% non USP* Earwax removal aid *pH differs from USP specifications	
Use 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 ■ recently had ear surgery ■ dizziness ■ an injury or perforation (hole) of the eardrum 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 a four day treatment with this product Keep 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. Remove any hearing aids before use Adults and children over 12 yrs of age: tilt head to the side and place 5 to 10 drops into the ear canal. ■ Tip of applicator should not enter into the ear canal ■ Keep drops in ear for several minutes by keeping head tilted sideways or placing cotton in the ear. ■ Use twice daily for up to 4 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 yrs of age: Consult a physician.	
Inactive Ingredients Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sarcosinate, Sodium Stannate, Purified Water.	
Questions & comments? 1-800-423-6967	
RETAIN OUTER CARTON FOR FULL LABELING.	

DIST. BY CAH DUBLIN OH, 43017 ©2022 Cardinal Health R 02/18/22
1-800-200-6315

100% Money Back Guarantee
Return to place of purchase if not satisfied.

CIN 5511647 REV. 6/22



LEADER EARWAX REMOVAL KIT

carbamide peroxide 6.50% kit liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0490
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	6.5 g in 100 mL	
Inactive Ingredients				
Ingredient Name			Strength	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)				
WATER (UNII: 059QF0KO0R)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
SODIUM STANNATE (UNII: NJ7C1V83KG)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0490-2	15 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/06/2019	04/30/2026
2	NDC:70000-0490-1	1 in 1 CARTON	05/06/2019	04/30/2026
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 Drug	M014	05/06/2019	04/30/2026	

Labeler - Cardinal Health, 110 dba Leader (063997360)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	pack(70000-0490) , label(70000-0490) , manufacture(70000-0490) , analysis(70000-0490)

Revised: 7/2025

Cardinal Health, 110 dba Leader