

TOPCARE EARWAX REMOVAL KIT- carbamide peroxide liquid
TOPCO ASSOCIATES LLC

TopCare Earwax Removal Kit

Drug Facts

Active ingredient

Carbamide peroxide 6.5%

Purpose

Earwax removal aid

Uses

for occasional use as an aid to soften, loosen, and remove excessive ear wax

Warnings

For use in the ear only

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 ear drum
- 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 4 days
- excessive ear wax remains after use of this product

Keep out of reach of children.

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

Directions

FOR USE IN THE EAR ONLY

Adults and children over 12 years of age:

- Tilt head sideways and 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 titled 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 years:consult a doctor

Other information

- Avoid exposing bottle to excessive heat and direct sunlight
- Store bottle in the outer carton
- Keep cap on bottle when not in use
- Product foams on contact with ear wax due to release of oxygen. There may be an associated crackling sound
- Do not use if tamper-evident safety seal is broken or missing

Inactive ingredients

- anhydrous citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, water

Questions?

1-888-423-0139

Package Labeling:



TOPCARE EARWAX REMOVAL KIT			
carbamide peroxide liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-835
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	65 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
WATER (UNII: 059QF0KO0R)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-835-33	1 in 1 CARTON	11/28/2014	
1		15 mL in 1 BOTTLE, DISPENSING; 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	11/28/2014	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Bell Pharmaceuticals, Inc.		140653770	manufacture(36800-835)

Revised: 2/2025

TOPCO ASSOCIATES LLC