

TOPCARE EARWAX REMOVAL DROPS- carbamide peroxide solution/ drops
Topco Associates LLC

TopCare Earwax Removal Drops

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 earwax

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 earwax 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

Adult 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 tilted 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 earwax due to release of oxygen. There may be an associated cracking 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?

1-800-328-5890

Package Labeling:



TOPCARE EARWAX REMOVAL DROPS

carbamide peroxide solution/ drops

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76162-836

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		
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
WATER (UNII: 059QF0KO0R)				
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76162-836-34	1 in 1 BOX	06/01/2015	
1		15 mL in 1 BOTTLE; 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	06/01/2015	

Labeler - Topco Associates LLC (006935977)

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Topco Associates LLC