

LEADER EARWAX REMOVAL DROPS EARWAX REMOVAL AID- carbamide peroxide solution/ drops
Cardinal Health, Inc.

Leader Earwax Removal Drops Earwax Removal Aid

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 (1-800-222-1222) 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 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
- Store bottle in the outer carton
- Store at 15-30°C (59-86°F)
- Keep cap on bottle when not in use
- Product foams on contact with earwax 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?

1-800-328-5890

Weekdays 8:30-5:00 CST

Package Labeling:

Carbamide Peroxide 6.5%
Earwax Removal Aid
safe & gentle

earwax removal drops

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

Drug Facts (continued)

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*This product is not manufactured or distributed by Medtech Products Inc. a Prestige Brands Company owner of the registered trademark Debrox®.

REV 3/24

Compare to Debrox®
active ingredient*

NDC XXXXX-XXX-XX

earwax removal drops

Carbamide Peroxide 6.5%
Earwax Removal Aid

safe & gentle



0.5 Fl Oz (15 mL)

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- 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
- Store at 15-30°C (59-86°F)

LEADER EARWAX REMOVAL DROPS EARWAX REMOVAL AID

carbamide peroxide solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0688
Route of Administration	TOPICAL		

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:70000-0688-1	1 in 1 BOX	07/09/2024	
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	07/09/2024	

Labeler - Cardinal Health, Inc. (063997360)