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 and direct sunlight
- 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:





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: 31PZ 2VAU81) (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: 059QF0K00R)	

Packaging

#	ltem 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		

- I	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)

Revised: 8/2024

Cardinal Health, Inc.