EARWAX REMOVAL AID- earwax removal aid liquid
Cardinal Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Earwax Removal Aid

Active ingredient(s)

Carbamide Peroxide 6.5%

Purpose

Earwax Removal Aid

Use(s)

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

Warnings

Warning

For External Use Only

Do not use

- In the eye
- for more than 4 days

Ask a doctor before use if you have

- ear drainage or discharge
- pain, irritation or rash in the ear
- had ear surgery
- an injury or perforation (hole) in the ear drum

Stop use and ask a doctor if

Stop use and ask a doctor if excessive earwax remains after use

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 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 my be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. Children under 12 years of age, consult a doctor.

Other information

Do not use if imprinted seal on cap is broken or missing.

Storage

- Store at controlled room temperature 15 to 30C (59 to 86F)
- KEEP IN A DRY PLACE

Principal Display Panel

Principle display panel:

Leader Ear Wax Box

Inactive Ingredients

anhydrous Glycerin

EARWAX REMOVAL AID

earwax removal aid liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37205-457
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 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	120.0 mg in 100 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37205-457-05	15 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC MONOGRAPH FINAL	part344	02/06/2012	

Labeler - Cardinal Health (097537435)

Registrant - Continental Manufacturing Chemist, Inc. (005278007)

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