

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 may 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 Drops
Earwax Removal Aid
Carbamide Peroxide (6.5%)

NDC 37205-457-05

LEADER®
Ear Drops
Earwax Removal Aid
Carbamide Peroxide (6.5%)

Drug Facts
(continued)

Other Information

- Store at controlled room temperature 15 to 30C (59 to 86F)
- Do not use if imprinted seal on cap is broken or missing.
- KEEP IN A DRY PLACE

Inactive Ingredients
anhydrous glycerin

All **Leader®** Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 2441095
www.myleader.com
1-800-200-6313

• Softens and removes excessive earwax safely and gently

• Safe, fast acting formula

CONTAINS ONE 0.5 FL. OZ. (15 ML) BOTTLE

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

Note: When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal.

Protect from heat and direct sunlight. Keep cap on bottle when not in use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

See back panel for complete directions

Tilt head and squeeze bottle

Drug Facts

Active Ingredient	Purpose
Carbamide Peroxide 6.5%	Earwax Removal Aid

Uses for occasional use as an aid to soften, loosen, and remove excessive earwax.

Warnings
For external use only

Do not use

- in the eyes
- 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) of the ear drum

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 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 of age: consult a doctor.

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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)

Revised: 11/2013

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