

**EARWAX REMOVAL KIT - earwax removal kit 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.*

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**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 Wax Removal Kit**  
Carbamide Peroxide (6.5%)

NDC 37206-458-03

**LEADER®**  
**Ear Wax Removal Kit**  
Carbamide Peroxide (6.5%)

**LEADER®**  
**Ear Wax Removal Kit**  
Carbamide Peroxide (6.5%)

**Drug Facts** (continued)

**Other information**

- Store at controlled room temperature 15 to 30C (59 to 98F)
- Do not use if imprinted seal on cap is broken or missing.
- KEEP IN A DRY PLACE

**Inactive ingredients**  
anhydrous glycerin

For occasional use as an aid to soften, loosen and remove excessive earwax. Please inspect ear syringe prior to use and replace if product shows any signs of wear.

**Note:** When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal. Keep cap on bottle when not in use. This product is not a toy. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**CLEANING & STORAGE:**  
Clean syringe with warm, soapy water and rinse thoroughly after each use. Shake out excess water and let air-dry thoroughly. Store in a cool, dry place, away from hot surfaces and sharp instruments. Do not expose product to direct sunlight or heat.

• **Softens and gently removes excessive earwax**

• **Fast acting formula**

• **Ear syringe included**

**100% SATISFACTION GUARANTEED**

**CONTAINS**  
0.5 fl oz (15 mL) EAR DROPS &  
ONE 0.7 oz (20 mL) EAR SYRINGE

**See back panel for complete directions**

Tilt head and squeeze bottle

Gently flush the ear with warm water

**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.

Questions or Comments? Call 1-800-328-2742

**FOR YOUR PROTECTION:** The bottle in this package has a tamper-resistant seal imprinted, "sealed for your protection", connecting the cap to the bottle. If the seal has been tampered with, DO NOT use this product.

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

Made in USA

DISTRIBUTED FOR  
CARDINAL HEALTH  
DUBLIN, OHIO 43017  
CIN 2893394  
www.myleader.com  
1-800-200-6313

Leader Ear Wax Kit Carton

## Inactive Ingredients

anhydrous Glycerin

## Questions or Comments?

Call 1-800-328-2742

# EARWAX REMOVAL KIT

earwax removal kit liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-458
<b>Route of Administration</b>	AURICULAR (OTIC)		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	6.5 mg in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
GLYCERIN (UNII: PDC6A3C0OX)	120.0 mg in 100 mL

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:37205-458-03	15 mL in 1 BOTTLE		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part344	02/06/2012	

**Labeler** - Cardinal Health (097537435)

**Registrant** - Continental Manufacturing Chemist, Inc. (005278007)

Revised: 11/2013

Cardinal Health