

**LEADER EARWAX REMOVAL KIT EARWAX REMOVAL AID AND BULB- carbamide peroxide**  
**Cardinal Health 110 DBA Leader**

-----  
**Leader Earwax Removal Kit, Earwax Removal Aid & Bulb**

***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 Labelling:**

Carbamide Peroxide 6.5%  
Earwax Removal Aid  
safe & gentle

# earwax removal drops

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

## Drug Facts (continued)

- 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

\*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)

# earwax removal drops

Carbamide Peroxide 6.5%  
Earwax Removal Aid  
safe & gentle



0.5 Fl Oz (15 mL)

## 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 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)

LOT & EXP AREA.  
NO INK IN THIS AREA

earwax  
removal  
kit

Carbamide Peroxide 6.5%  
Earwax Removal Aid  
safe & gentle



00000000000000000000

Compare to Debrox® active ingredient\*  
NDC XXXXX-XXX-XX

earwax  
removal  
kit

Carbamide Peroxide 6.5%  
Earwax Removal Aid  
safe & gentle



0.5 Fl Oz (15 mL)  
washer bulb included

earwax  
removal  
kit

Carbamide Peroxide 6.5%  
Earwax Removal Aid  
safe & gentle



0.5 Fl Oz (15 mL)  
washer bulb included

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

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

LOT & EXP AREA  
NO INK IN THIS AREA

REV 3/24

## LEADER EARWAX REMOVAL KIT EARWAX REMOVAL AID AND BULB

carbamide peroxide kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0689
--------------	----------------	--------------------	----------------

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0689-1	1 in 1 BOX	07/09/2024	
1		1 in 1 KIT		

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	15 mL

Part 1 of 1

LEADER EARWAX REMOVAL DROPS EARWAX REMOVAL AID

carbamide peroxide solution/ drops

Product Information

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		
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	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	07/09/2024	

Revised: 7/2024

Cardinal Health 110 DBA Leader