

EAR WAX REMOVING DROPS CARBAMIDE PEROXIDE- leader 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.

Drug Facts

Active Ingredient

Carbamide Peroxide 6.5%

Purpose

Carbamide Peroxide 6.5%

Uses

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

Warnings

Do not use: if you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor. If you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor. For more than four consecutive days.

When using this product: avoid contact with the eyes.

Stop use and ask a doctor if: excessive ear wax remains after use of this product for four consecutive days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.

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 ear. Use twice daily for up to four 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.

Inactive ingredients

Glycerin, Oxyquinoline, Aloe Barbadensis Leaf Extract, Anthemis Nobilis Flower Oil

Ear Wax Cleansing Kit

Step 1 Ear Wax Removing Drops

Step 2 Ear Cleansing Spray

Directions: For use in the ear only. Adults and children over 12 years of age: tilt head sideways and place 5-10 drops into ear. Tip of applicator should not enter ear canal. Keep drops in the ear for several minutes by keeping your head tilted or placing cotton in your ear. Use twice daily for up to four 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. **Active ingredient:** Carbamide Peroxide 6.5% in anhydrous glycerin. Note: LEADER® ear drops will foam on contact with ear wax due to the release of oxygen. Also, heating before use is not recommended. **Warnings:** Do not use if you have drainage or discharge, ear pain, irritation, or rash in the ear or are dizzy. Consult a doctor. Do not use if you have any perforation (hole) of the eardrum or after ear surgery unless directed by a doctor. Do not use for more than four days. If excessive earwax remains after use of this product, consult a doctor. Do not use if tamper evident shrink film is broken or missing. **Cautions:** Avoid exposing bottle to excessive heat and direct sunlight. Keep cap on bottle when not in use. Avoid contact with eyes. **Keep this and all drugs out of the reach of children.** In case of accidental ingestion, seek professional assistance or contact a Poison Control Center.

NDC 37205-615-56



Ear Wax Removing Drops

Step 1

- Carbamide Peroxide 6.5%
- With chamomile & aloe
- Safe, fast acting
- Alcohol free



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www.myleader.com 1-800-200-6313

NET WT. 0.5 FL OZ (15 mL)

Ear Wax Cleansing Kit



Ear Wax Cleansing Kit

Drug Facts

Active ingredient	Purpose
Carbamide Peroxide 6.5%	Softens & Removes Wax

Uses
For occasional use as an aid to soften, loosen, and remove excessive ear wax.

Warnings
Do not use
• If you have ear drainage or discharge, ear pain, irritation or rash in the ear, or are dizzy, consult a doctor.
• If you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor.
• For more than four consecutive days.

When using this product
• avoid contact with the eyes.

Stop use and ask a doctor if • excessive ear wax remains after use of this product for four consecutive days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.

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 ear. • Use twice daily for up to four 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 • Protect from heat and direct sunlight. • Keep cap on bottle when not in use.

Inactive ingredients
Glycerin, Oxycyanoline, Aloe Barbadensis Leaf Extract, Chamomile Arvensis Nabalis Flower Oil.

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

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Step 2 Ear Cleansing Spray

DIRECTIONS: Tilt head to the side, insert tip of nozzle to the downward pointing ear and activate, allowing liquid to flow from ear. Tilt head to the other side and repeat. It is recommended that application takes place over a sink.

SUGGESTED USE: 1-2 applications after each use of LEADER® Ear Wax Removing Drops or can be used alone 3 or more times per week.

- WARNINGS:** LEADER® Ear Cleansing Spray should NOT be used in the following situations:
- Children under 12 years of age
 - Individuals with tubes in their ears
 - Individuals with otitis or other ear infections
 - Individuals with (current or previous) perforated eardrums
 - Individuals who have had mastoid surgery
 - Individuals suffering from Meniere's Syndrome or those experiencing any form of dizziness, vertigo, hardness of hearing or other ear problems
 - For the purpose of removing ear wax. Impacted ear wax should be removed by a health care professional prior to use of LEADER® Ear Cleansing Spray
 - Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. Keep out of reach of children.

INGREDIENTS: Sea Water*, Paraben free, Hypoallergenic.
*Isotonic, Desalinated, 100% Natural.

Dieline Information 080689Q4

Ear Wax Cleansing Kit

**Step 1
Ear Wax Removing Drops**
• Safe, fast acting
• With chamomile & aloe

**Step 2
Ear Cleansing Spray**
• 100% Natural Seawater
• Rinses away build up



Step 1 Ear Wax Removing Drops

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. Top of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in ear.

FDA APPROVED USES: For occasional use as an aid to soften, loosen and remove excessive ear wax.



CONTAINS:
1 - 0.5 FL OZ (15 mL) BOTTLE
1 - 3.3 FL OZ (98 mL) SPRAY

080689Q4



EAR WAX REMOVING DROPS CARBAMIDE PEROXIDE

leader liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-615
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Carbamide Peroxide (UNII: 31PZ2VAU81) (Carbamide Peroxide - UNII:31PZ2VAU81)	Carbamide Peroxide	6.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-615-56	1 in 1 PACKAGE, COMBINATION		
1		15 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	12/01/2011	

Labeler - Cardinal Health (097537435)

Revised: 1/2012

Cardinal Health