

AUDIOLOGISTS CHOICE EARWAX REMOVAL AID DROPS- carbamide peroxide solution/ drops
Oaktree Products Inc

Audiologists Choice Earwax Removal Aid Drops

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 right away.

Directions

FOR USE IN THE EAR ONLY

Adult 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
- Keep cap on bottle when not in use
- Product foams on contact with earwax due to release of oxygen. There may be an associated cracking 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?

1-800-347-1960

Package Labeling:

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION.

AUDIOLOGIST'S CHOICE

<p>Drug Facts</p> <p>Active ingredient Purpose Carbamide peroxide 6.5%.. Earwax removal aid</p> <p>Uses for occasional use as an aid to soften, loosen, and remove excessive earwax</p> <p>Warnings For use in the ear only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> 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 <p>When using this product avoid contact with the eyes</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you need to use for more than 4 days excessive earwax remains after use of this product <p>Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</p>	<p>Drug Facts (continued)</p> <p>Directions FOR USE IN THE EAR ONLY Adults and children over 12 years of age:</p> <ul style="list-style-type: none"> 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 <p>Children under 12 years: consult a doctor</p> <p>Other information</p> <ul style="list-style-type: none"> Avoid exposing bottle to excessive heat and direct sunlight Store bottle in the outer carton 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
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OAKTREE
products

Distributed By:
Oaktree Products Inc.
St. Louis, Mo. 63005
Made in U.S.A.

*This product is not manufactured or distributed by Prestige Brands Inc. owner of the registered trademark Debrox®.

REV 02/14



Drug Facts (continued)

Inactive ingredients

- anhydrous citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, water

Questions? 1-800-347-1960

AUDIOLOGIST'S CHOICE
EARWAX REMOVAL AID
Carbamide Peroxide 6.5%
Safe, Gentle, Non-Irritating
0.5 Fl Oz (15 mL)



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Compare to Debrox®
active ingredient*
NDC 59256-001-01



AUDIOLOGISTS CHOICE EARWAX REMOVAL AID DROPS

carbamide peroxide solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59256-836
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	65 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59256-836-34	1 in 1 CARTON	06/01/2016	
1		15 mL in 1 BOTTLE, DISPENSING; 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	06/01/2016	

Labeler - Oaktree Products Inc (800748329)

Establishment

Name	Address	ID/FEI	Business Operations
Bell Pharmaceuticals, Inc.		140653770	manufacture(59256-836)