AUDIOLOGISTS CHOICE EARWAX REMOVAL SYSTEM EARWAX REMOVAL -
carbamide peroxide liquid
Oaktree Products Inc.

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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Audiologist’s Choice EARWAX REMOVAL SYSTEM Earwax Removal

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
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
- 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

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

Distributed By: Oaktree Production Inc. St. Louis, Mo.63005 Made In USA
Audiologist's Choice Earwax Removal Aid Carbamide Peroxide 6.5% Safe, Gentle, Non-Irritating Compare to Debrox active ingredient Washer Bulb Included 0.5 FL OZ (15mL)

Product Labels
# AUDIOLOGISTS CHOICE EARWAX REMOVAL SYSTEM EARWAX REMOVAL
carbamide peroxide liquid

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>NDC:59256-001</th>
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<tbody>
<tr>
<td><strong>Route of Administration</strong></td>
<td><strong>TOPOCAL</strong></td>
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## Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)</td>
<td>CARBAMIDE PEROXIDE</td>
<td>65 mg in 1 mL</td>
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## Inactive Ingredients

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<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)</td>
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<tr>
<td>GLYCERIN (UNII: PDC6A3C00X)</td>
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<tr>
<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<tr>
<td>SODIUM CITRATE (UNII: 1Q73Q2JULR)</td>
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<tr>
<td>SODIUM LAURYL SULFATE (UNII: 368GB5141J)</td>
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<td>WATER (UNII: 059QF0KO0R)</td>
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## Packaging

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<th>Package Description</th>
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<td>1 in 1 CARTON</td>
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### Marketing Information

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<td>OTC monograph final</td>
<td>part344</td>
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### Labeler - Oaktree Products Inc. (800748329)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
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<th>ID/FEI</th>
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<td>Bell Pharmaceuticals, Inc.</td>
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<td>140653770</td>
<td>manufacture(59256-001)</td>
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Revised: 12/2014