

**EAR WAX REMOVAL AID - carbamide peroxide liquid**  
**Continental Manufacturing Chemist, 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.*

-----  
**DIRECTIONS: For use in the ear only.** For use by 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 4 days, if needed or as directed by a physician. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe. For children under 12 years of age, consult a physician. NOTE: When the ear canal is irrigated, the tip of the ear syringe should not obstruct the flow of water leaving the ear canal.

**WARNINGS: DO NOT USE** if you have ear drainage or discharge, ear pain, irritation, or rash in the ear, or if you are dizzy; consult a physician. **DO NOT USE** if you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a physician. **DO NOT USE** for more than 4 days; if excessive earwax remains after use of this product, consult a physician. Avoid contact with eyes. If swallowed, get medical help or contact a Poison Control Center right away.

**ACTIVE INGREDIENT:** Carbamide Peroxide 6.5%

**KEEP OUT OF REACH OF CHILDREN**

Softens and removes excessive earwax safely and gently.

**Inactive Ingredient:** anhydrous glycerin

**Uses** for occasional use as an aid to soften, loosen and remove excessive earwax.

<b>EAR WAX REMOVAL AID</b>				
carbamide peroxide liquid				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49794-003	
<b>Route of Administration</b>	AURICULAR (OTIC)			
<b>Active Ingredient/Active Moiety</b>				
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
	carbamide peroxide (UNII: 31PZ2VAU81) (carbamide peroxide - UNII:31PZ2VAU81)	carbamide peroxide	6.5 mg in 100 mL	
<b>Inactive Ingredients</b>				
	<b>Ingredient Name</b>	<b>Strength</b>		
	glycerin (UNII: PDC6A3C0OX)			
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:49794-003-15	15 mL in 1 BOTTLE, DROPPER		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	08/27/2010	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Continental Manufacturing Chemist, Inc.		005278007	manufacture

Revised: 3/2011

Continental Manufacturing Chemist, Inc.