ENT ESSENTIALS EAR WAX REMVOER- carbamide peroxide liquid
Wisconsin Pharmacal Company

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.

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

Aska 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 eardrum
- recently had ear surgery

When using this product avoid contact wtih the eyes

Stop use and aks a doctor if

- you need to use for more than four 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 immediately.

D **irections**

FOR USE IN THE EAR ONLY Adults and children over 12 years of age:

tilt head sideways
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 four days if needed, or as directed by a doctor
any wax remaining after treatment may be removed by gently flusing the ear with warm water, using a soft rubber bulb ear syringe.

Children under 12 years: consult a doctor.

Other informaiton

- store bottle in teh outer carton
- product foams on contact with earwax due to the release of oxygen. Theremay be an associated "crackling" sound
- keep cap on bottle when not in use

Inactive ingredients

Glycerin, Polysorbate 20, Propylene glycol, Sodium citrate, Tartaric acid

Questions or comments? 1-800-635-3696

ENT ESSENTIALS EAR WAX REMVOER

carbamide peroxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68093-4503
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	0.065 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
TARTARIC ACID (UNII: W4888I119H)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68093-4503-1	1 in 1 CARTON	02/01/2017	
1		22 g 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 not final	part356	02/01/2017	

Labeler - Wisconsin Pharmacal Company (800873986)

Establishment

Name	Address	ID/FEI	Business Operations
Wisconsin Pharmacal Company		800873986	manufacture(68093-4503)

Revised: 11/2017 Wisconsin Pharmacal Company