

AURALYT- carbamide peroxide liquid
Menper Distributors, 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.

Active Ingredient

Carbamide Peroxide 6.5%.....Earwax removal aid

Purpose

Earwax removal aid

Uses

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

AVOID CONTACT WITH EYES

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 ear drum or after ear surgery unless directed by a doctor
- for more than 4 days; if excessive ear wax remains after use of this product, consult a doctor.

keep out of reach of children.

if pregnate or breast-feeding

ask a health professional before use.

In case of accidental indegestion, 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 soft rubber bulb ear syringe.
- Children under 12 years of age: consult a doctor.

Other information

Store this product between 15° to 30° C (59°-86° F)

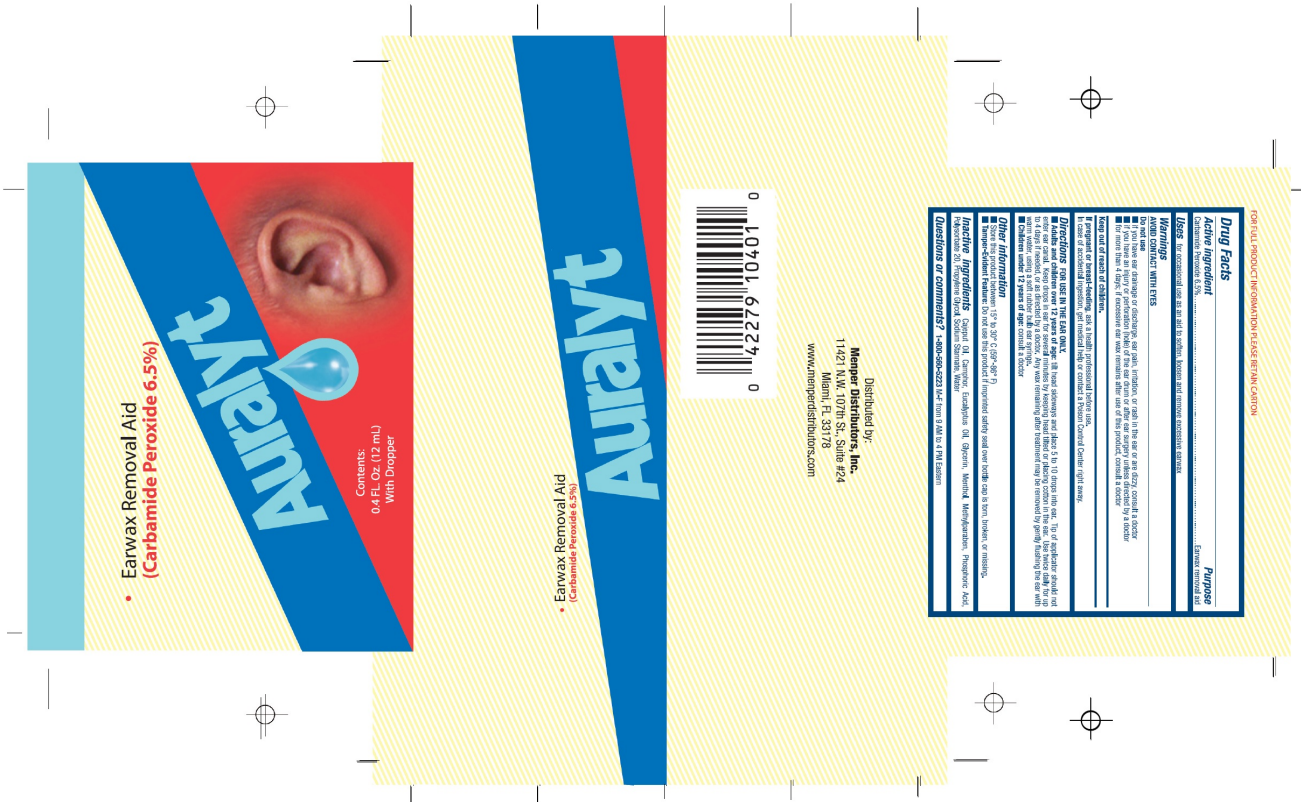
Tamper-Evident Feature: Do not use this product if imprinted safety seal over bottle cap is torn, broken, or missing

Inactive ingredients

Cajeput oil, camphor, eucalyptus oil, glycerin, menthol, methylparaben, phosphoric acid, polysorbate 20, propylene glycol, sodium stannate, water

Questions or comments?

1-800-560-5223 M-F from 9 AM to 4 PM Eastern.



Auralyt
 Earwax Removal Aid
 (Carbamide Peroxide 6.5%)

Contents:
 0.4 FL. OZ. (12 mL)
 With Dropper

Auralyt
 Earwax Removal Aid
 (Carbamide Peroxide 6.5%)



Distributed by:
Mergent Distribution, Inc.
 1102
 Miami, FL 33178
 www.mergentdistributions.com

Drug Facts

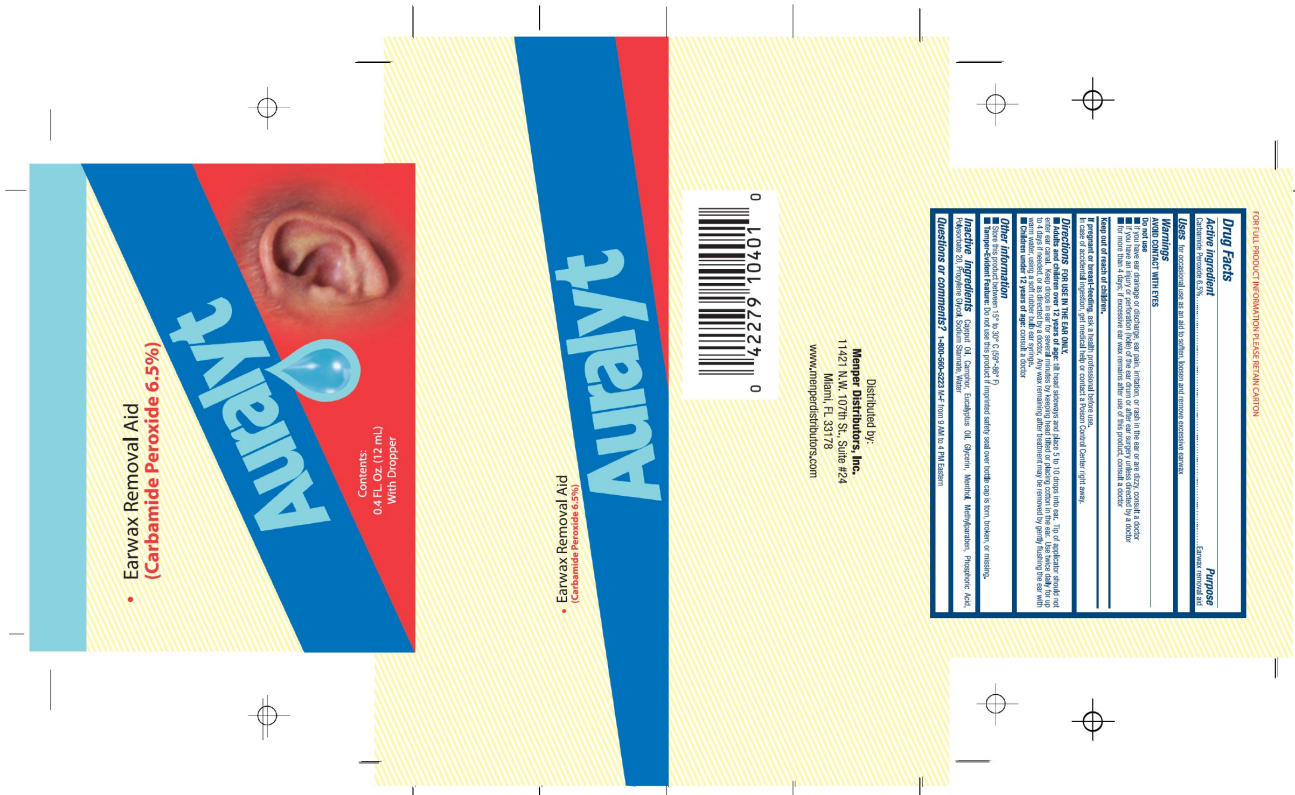
Active ingredient: Carbamide Peroxide 6.5%

Warnings: Use as directed. Use in an adult or child. Remove and remove earwax.

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AURALYT

carbamide peroxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53145-311
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	7.8 mg in 12 mL

Inactive Ingredients

Ingredient Name	Strength
CAJUPUT OIL (UNII: J3TO6BUQ37)	
CAMPHOR (NATURAL) (UNII: N20HL7Q941)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PHOSPHORIC ACID (UNII: E4GA8884NN)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STANNATE (UNII: NJ7C1V83KG)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53145-311-04	1 in 1 CARTON	01/01/2014	
1		12 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	01/01/2014	

Labeler - Menper Distributors, Inc (101947166)

Revised: 2/2020

Menper Distributors, Inc