

CARBAMIDE PEROXIDE 6.5%- earwax removal kit solution/ drops
Allegiant Health

488 - Earwax Removal Kit

Active ingredient(s)

Carbamide peroxide 6.5%

Purpose

Earwax removal aid

Use(s)

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

Warnings

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

When using this product

- avoid contact with eyes. If accidental contact with eyes occurs, flush eyes with water and consult a doctor

Keep out of reach of children

If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

FOR USE IN 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.

Children under 12 years of age: consult a doctor

Other information

- do not store above 86°F (30°C)
- protect from heat and direct sunlight
- DO NOT USE IF SHRINKBAND ON BOTTLE IS BROKEN OR MISSING
- Product foams on contact with earwax due to the release of oxygen. There may be an associated “crackling” sound.
- Keep cap on bottle when not in use
- Retain carton for full product information.

Inactive ingredients

citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, tartaric acid

Questions/Comments

Call **1-888-952-0050**

(Monday-Friday 9 AM – 5 PM EST)

Principal Display Panel

The Principal Display Panel (PDP) for HealthAid EarWax Removal Drops is a rectangular label with a yellow top section and a blue bottom section. The top section contains the product name and active ingredient information. The bottom section contains safety and volume information. The central part of the label is a white background with black text, containing detailed product information.

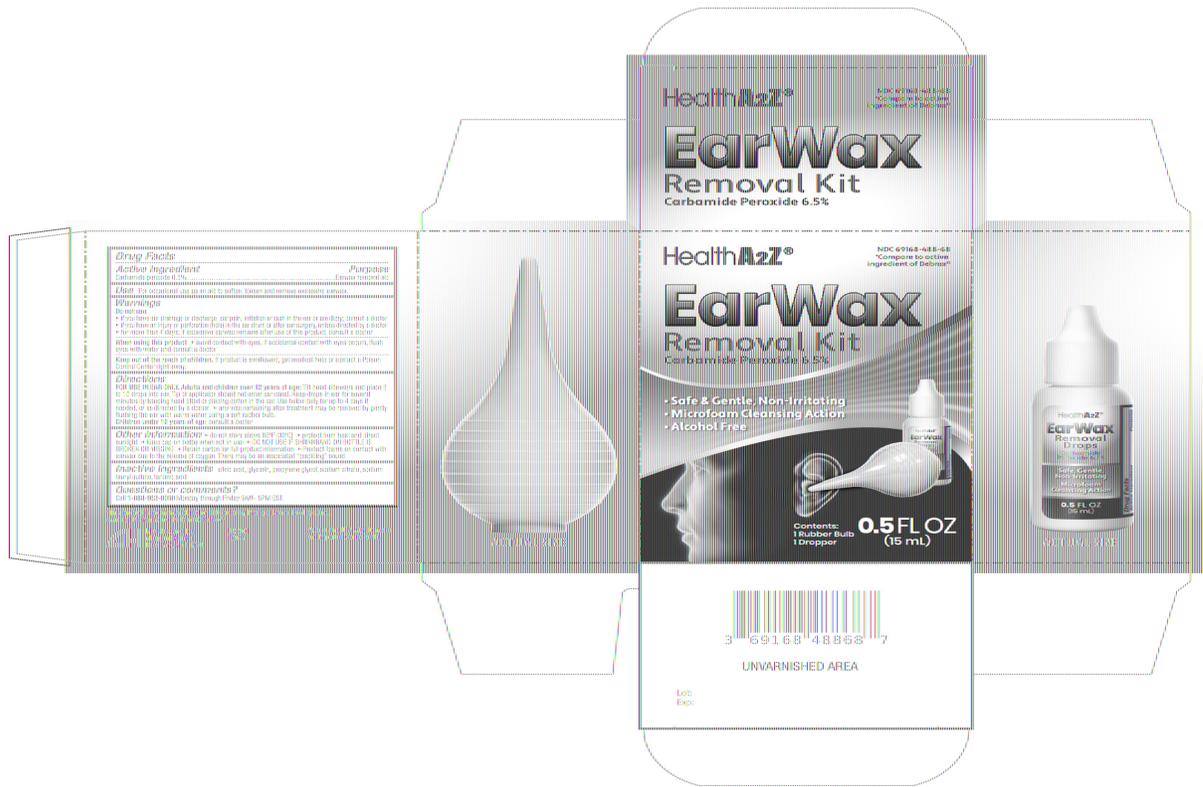
HealthAid®
EarWax Removal Drops
Carbamide Peroxide 6.5%

Safe, Gentle, Non-Irritating
Microfoam Cleansing Action

0.5 FL OZ (15 mL)

Drug Facts
Purpose Carbamide peroxide 6.5%.....Earwax removal aid
Active ingredient Carbamide peroxide 6.5%.....Earwax removal aid
Use For occasional use as an aid to soften, loosen and remove excessive earwax
Warnings 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) in the ear drum or after ear surgery, unless directed by a doctor • For more than 4 days, if excessive earwax remains after use of this product, consult a doctor
When using this product • avoid contact with eyes. If accidental contact with eyes occurs, flush eyes with water and consult a doctor
Keep out of the reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.
Directions FOR USE IN 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. Children under 12 years of age, consult a doctor
Inactive ingredients citric acid, glycerin, propylene glycol, sodium citrate, sodium lauryl sulfate, tartaric acid
Manufactured for: Allegiant Health
Deer Park, NY 11729
LB2399
R0825

Earwax label



Earwax carton

CARBAMIDE PEROXIDE 6.5%

earwax removal kit solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-488
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
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TARTARIC ACID (UNII: W4888119H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-488-68	1 in 1 CARTON	10/28/2025	
1		15 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 Drug	M014	10/28/2025	

Labeler - Allegiant Health (079501930)

Revised: 10/2025

Allegiant Health