

**CAREONE EARWAX REMOVAL DROPS- carbamide peroxide solution/ drops**  
**Retail Business Services, LLC**

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**CareOne Earwax Removal Drops**

***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

**Package Labeling:**



## CAREONE EARWAX REMOVAL DROPS

carbamide peroxide solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-838
<b>Route of Administration</b>	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	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-838-34	1 in 1 BOX	01/01/2020	
1		15 mL 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 Drug		M014	01/01/2020	

**Labeler** - Retail Business Services, LLC (967989935)

## Establishment

Name	Address	ID/FEI	Business Operations
Bell Pharmaceuticals, Inc.		140653770	manufacture(72476-838)

Revised: 12/2023

Retail Business Services, LLC