

## **CAREONE EARWAX REMOVAL DROPS- carbamide peroxide solution/ drops**

**Retail Business Services, LLC**

*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.*

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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: 059QF0K00R)	

### 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 final	part344	01/01/2020	

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

### Establishment

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

Revised: 3/2020

Retail Business Services, LLC