

**FAMILY WELLNESS EARWAX REMOVAL EARWAX AND BULB- carbamide peroxide**

**Family Dollar Services Inc**

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**Family Wellness-Earwax Removal Kit, Earwax & Bulb**

***Drug Facts***

***Active ingredients***

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 (1-800-222-1222) 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
- Do not store above 25°C (77°F)
- 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:**



## FAMILY WELLNESS EARWAX REMOVAL EARWAX AND BULB

carbamide peroxide kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-835
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-835-01	1 in 1 KIT	11/01/2019	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKAGE	15 mL

### Part 1 of 1

## FAMILY WELLNESS EARWAX REMOVAL

carbamide peroxide solution/ drops

## Product Information

**Route of Administration** AURICULAR (OTIC)

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CARBAMIDE PEROXIDE</b> (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	65 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-836-01	1 in 1 BOX		
1		15 mL in 1 PACKAGE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	11/01/2019	

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OTC Monograph Drug	M014	11/01/2019	

**Labeler** - Family Dollar Services Inc (024472631)

## Establishment

Name	Address	ID/FEI	Business Operations
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Bell Pharmaceuticals, Inc.

140653770

manufacture(55319-835)

Revised: 2/2025

Family Dollar Services Inc