

FAMILY WELLNESS EARWAX REMOVAL EARWAX AND BULB- carbamide peroxide

Family Dollar Services Inc

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 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:



FAMILY WELLNESS EARWAX REMOVAL EARWAX AND BULB carbamide peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
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: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
Bell Pharmaceuticals, Inc.		140653770	manufacture(55319-835)

