

## **EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid**

### **Premier Value**

*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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### **Drug Facts**

#### **Active ingredient**

Carbamide peroxide 6.5%

#### **Purpose**

Earwax removal aid

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

### **Warnings**

**Ask doctor before use if you have** • ear drainage or discharge • ear pain • irritation or rash in ear • dizziness • an injury or perforation (hole) of the eardrum • recently had ear surgery

**When using this product** avoid contact with eyes

**Stop and ask doctor before use if** • you need to use for more than four days • excessive earwax remains after use of this product

#### **Keep out of reach of the children**

If product is 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 of age: consult a doctor.**

Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water

### **Questions?**

**866-483-2846**

**Drug Facts (continued)**

**Other information**

- do not store above 86°F (30°C)
- store bottle in the outer carton
- product foams on contact with ear wax due to release of oxygen. There may be an associated "crackling" sound.
- keep cap on bottle when not in use

**Inactive ingredients** Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water.

**Questions?**  
866-483-2846

DISTRIBUTED BY  
CHAIN DRUG CONSORTIUM  
3301 NW BOCA RATON BLVD  
SUITE 101 BOCA RATON, FL 33431  
MADE IN USA WITH USA AND IMPORTED MATERIALS

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

\*COMPARE TO THE ACTIVE INGREDIENT IN DEBROX®



**Ear Wax Removal Drops**

**EAR WAX REMOVAL AID**

Carbamide Peroxide 6.5%

Safe, Gentle,  
Non-Irritating Drops

0.5 FL OZ (15 mL)



**Ear Wax Removal Drops**  
EAR WAX REMOVAL AID

**DO NOT USE IF SAFETY SEAL IS TORN OR MISSING**

**Drug Facts**

Active ingredient	Purpose
Carbamide Peroxide 6.5%.....	Ear wax removal aid

**Uses** for occasional use as an aid to soften, loosen and remove excessive ear wax

**Warnings**

**Do not use if you have**

- ear drainage or discharge
- irritation or rash in the ear
- an injury or perforation (hole) of the eardrum
- recently had ear surgery
- ear pain
- dizziness

**When using this product** avoid contact with the eyes

**Do not use if** you need to use for more than four days • excessive ear wax remains after use of this product

**Keep this and all drugs out of the 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 • 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 four 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

**IMPORTANT:**  
Keep this carton for future reference on full labeling.

\*This product is not manufactured or distributed by Prestige Brands Inc., owner of the registered trademark Debrox®.

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## EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-271
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	6.5 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Lauroyl Sarcosinate (UNII: 632GS99618)	
Sodium Stannate (UNII: NJ7C1V83KG)	
Water (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-271-01	1 in 1 CARTON	05/12/2014	
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	05/12/2014	

**Labeler** - Premier Value (101668460)

**Registrant** - Product Quest Mfg. (927768135)

## Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(68016-271) , label(68016-271)

Revised: 8/2018

Premier Value