

## **EAR WAX REMOVAL SYSTEM RITE AID- carbamide peroxide - 6.50%**

### **Rite Aid**

*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 Kit**

#### **Active ingredient**

Carbamide Peroxide - 6.50%

#### **Purpose**

Earwax removal aid

#### **Uses**

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

#### **Warnings**

**For external use only**

#### **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.**

#### **Other information**

- Protect from heat and direct sunlight
- Keep cap on bottle when not in use

#### **Inactive ingredient**

Aloe Barbadensis Leaf Extract

Chamomilla Recutita (Matricaria) Flower Extract

Glycerin

Mineral Oil

Oxyquinoline Sulfate

Water



# ear care earwax cleansing system

carbamide peroxide 6.5%

1 - 0.5 FL OZ (15 mL) BOTTLE  
1 - 3.3 FL OZ (98 mL) SPRAY

safe, effective earwax removal  
and cleansing system



# ear care earwax cleansing system

carbamide peroxide 6.5%

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## STEP 1:

### Earwax Removal Drops

- safe, fast acting
- alcohol free

## STEP 2:

### Ear Cleansing Spray

- rinses away earwax buildup



1 - 0.5 FL OZ (15 mL) BOTTLE  
1 - 3.3 FL OZ (98 mL) SPRAY



# ear care earwax cleansing system

carbamide peroxide 6.5%

### 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, ear pain, irritation or rash in the ear, or are dizzy; consult a doctor.
- if you have an injury or perforation (hole) of the eardrum or after ear surgery, unless directed by a doctor.
- for more than four consecutive days.

#### When using this product

- avoid contact with the eyes

**Stop use and ask a doctor if** • excessive ear wax remains after use of this product for four consecutive days.

**Keep out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.

### 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 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.

**Other information** • Protect from heat and direct sunlight. • Keep cap on bottle when not in use.

**Inactive ingredients** Aloe Barbadosensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Glycerin, Mineral Oil, Oxyquinoline Sulfate, Water.



ITEM 0370228

**RITE AID PHARMACY**

ear care  
**earwax cleansing system**

carbamide peroxide 6.5%

**STEP 1:**  
Earwax Removal Drops

**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. Top of applicator should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in ear.  
READ ADDITIONAL WARNINGS ON DRUG FACTS PANEL

**STEP 2:**  
Ear Cleansing Spray

**DIRECTIONS:** Tilting head to the side, insert tip of nozzle to the downward pointing ear and activate, allowing liquid to flow from ear. Tilt head to the other side and repeat. It is recommended that application takes place over a sink.  
**SUGGESTED USE:** 1-2 applications after each use of Rite Aid® Pharmacy Earwax Removal Drops or can be used alone 3 or more times per week.  
**WARNINGS:** Rite Aid® Pharmacy Ear Cleansing Spray should NOT be used in the following situations:

- Children under 12 years of age
- Individuals with tubes in their ears
- Individuals with otitis or other ear infections
- Individuals with (current or previous) perforated eardrums
- Individuals who have had mastoid surgery
- Individuals suffering from Meniere's syndrome or those experiencing any form of dizziness, vertigo, hardness of hearing or other ear problems
- For the purpose of removing earwax. Impacted earwax should be removed by a health care professional prior to use of Rite Aid® Pharmacy Ear Cleansing Spray

Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F. Keep out of reach of children.

**INGREDIENTS:** Water, Sodium Chloride, DMDM Hydantoin. Paraben free, Hypoallergenic.

ACTUAL SIZE

**RITE AID PHARMACY**

ear care  
**earwax cleansing system**

carbamide peroxide 6.5%

safe, effective ear wax removal and cleansing system

**STEP 1:**  
Earwax Removal Drops

- safe, fast acting
- alcohol free

**STEP 2:**  
Ear Cleansing Spray

- rinses away earwax buildup

1 - 0.5 FL OZ (15 mL) BOTTLE  
1 - 3.3 FL OZ (98 mL) SPRAY

## EAR WAX REMOVAL SYSTEM RITE AID

carbamide peroxide - 6.50% kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-1225
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1225-7	1 in 1 KIT	10/07/2011	

**Quantity of Parts**

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

**Part 1 of 1****EAR WAX REMOVAL DROPS RITE AID**

carbamide peroxide - 6.50% solution/ drops

**Product Information**

Item Code (Source)	NDC:11822-1226
Route of Administration	TOPICAL

**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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
Glycerin (UNII: PDC6A3C0OX)	
Oxyquinoline Sulfate (UNII: 61VUG75Y3P)	
Mineral Oil (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1226-1	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	10/07/2011	

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OTC monograph final	part344	10/07/2011	

**Labeler** - Rite Aid (014578892)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768 135	manufacture(118 22-1226) , pack(118 22-1225)

Revised: 6/2018

Rite Aid