

**EARCLEARRX- carbamide peroxide solution/ drops**  
**Nuance Medical, 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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**EarClearRx™**

**ACTIVE INGREDIENT**

Carbamide Peroxide USP 6.5%

**USES**

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

**WARNINGS**

Ask a doctor before use if you have ear drainage, discharge, ear pain, irritation or rash in the ear, dizziness, had an injury or perforation of the ear drum. When using this product avoid contact with the eyes. Stop use and ask a doctor if you need to use for more than four days.

Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222).

**DIRECTIONS**

FOR USE IN THE EAR ONLY. Tilt head sideways, place 5-10 drops in the ear, tip of the applicator should not enter the ear canal. Keep drops in the 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 an ear irrigation system.

**INACTIVE INGREDIENTS**

Glycerin, Propylene Glycol, Sodium Bicarbonate, Lactic Acid, Purified Water

Children under 12 years of age: consult a doctor before use.

**Other information**

Do not store above 25°C (77°F).

**Question or Comments**

(760) 362-8411

Distributed by: Nuance Medical LLC

## PRINCIPAL DISPLAY PANEL - 15 mL Bottle Label

EARCLEAR Rx™

EAR WAX  
REMOVAL  
DROPS

Active ingredients:  
Carbamide Peroxide USP 6.5%

0.5 FL OZ (15 mL)  
NDC: 74318-102-05

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Made in USA

## EARCLEARRx

carbamide peroxide solution/ drops

### Product Information

|                                |                  |                           |               |
|--------------------------------|------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG   | <b>Item Code (Source)</b> | NDC:74318-102 |
| <b>Route of Administration</b> | 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>GLYCERIN</b> (UNII: PDC6A3C00X)                      |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)              |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                         |          |
| <b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)            |          |
| <b>LACTIC ACID, UNSPECIFIED FORM</b> (UNII: 33X04XA5AT) |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:74318-102-05 | 15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | 01/01/2022           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part344                                  | 01/01/2022           |                    |

**Labeler** - Nuance Medical, LLC (078797666)

Revised: 11/2021

Nuance Medical, LLC