

SUAVEAR EARWAX REMOVAL AID- earwax removal aid solution/ drops
NEILMED PHARMACEUTICALS INC

New Neilmed SuavEar Earwax Removal Aid

Active Ingredient

Carbamide Peroxide 6.5%

Purpose

Earwax Removal Aid

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 or discharge
- Ear Pain
- Irritation or rash in the ear
- Dizziness
- An injury or perforation (hole) of the eardrum
- 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 3 days in a row

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 12 years of age:

- Tilt head sideways
- Place 5 to 10 drops into the ear, making sure that the tip of the applicator does not

enter the ear canal

- Keep drops in the ear for several minutes, either by using the included earplugs or keeping the head tilted to the side
- Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using the enclosed soft silicone bulb
- Use twice daily for up to four days, or as directed by a doctor

Children under 12 years: consult a doctor

Other Information

- Store bottle in the outer carton
- Product foams on contact with earwax due to release of oxygen. There may be associated "crackling" sound.
- Keep cap on bottle when not in use

Inactive Ingredients

Glycerin

Oxyquinoline

Product label : SuavEar Earwax Removal Aid

1 FREE TOOL
NeilMed
EAR SPIN SAFE
DOCTOR DEVELOPED • Soft • Flexible • Multi-Use
EAR CLEANING TOOL

NeilMed
SuavEar
EARWAX REMOVAL AID
Carbamide Peroxide 6.5%
FOR OCCASIONAL AID TO SOFTEN, LOOSEN AND REMOVE EXCESSIVE EARWAX

Includes: Drainage Collection Cup, Complete 2-step system, Softly removes excessive earwax.

Contents: 1 bottle of ear drops 15 ml (0.5 fl oz), 1 drainage collection cup, 2 ear plugs, 1 ear softening tool and 1 soft silicone ear syringe. Colors of parts may vary.

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| Drug Facts | Purpose |
|--|--------------------|
| Active Ingredient Carbamide Peroxide 6.5% | Earwax removal aid |
| Use: For occasional use as an aid to soften, loosen and remove excessive ear wax. | |
| Warnings Ask a doctor before use if you have: Ear drainage or discharge Ear pain or infection or rash in the ear • Discharge • An injury or perforation (hole) in the eardrum • Recently had ear surgery When using this product avoid contact with the eyes Stop use and ask a doctor if: • The wax is not gone for more than 3 days in a row Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| Use Directions FOR USE IN THE EAR ONLY Adults and children 12 years of age: • Fill the collection cup with 2 to 3 drops into the ear, making sure the tip of the syringe does not enter the ear canal. Keep drops in the ear for several minutes, either by using the included ear plug or holding the head tilted to the side. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using the included soft silicone bulb. Use twice daily for up to four days, or as directed by a doctor. Children under 12 years: consult a doctor. | |
| Other Information • Store bottle in the outer carton • Product foams on contact with ear wax due to release of oxygen. There may be associated "crackling" sound. • Keep cap on bottle when not in use. Contains approximately 100 mg Carbamide Peroxide. | |

Do not use if packaging is damaged

MANUFACTURED BY: 801 Avenida Blvd., Santa Rosa, CA 95403 USA
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ISO 13485:2012 International Accreditation
Quality Management System Certified Company
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NDC 13708-238-08
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SUAVEAR EARWAX REMOVAL AID

earwax removal aid solution/ drops

Product Information

| | | | |
|--------------------------------|------------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13709-312 |
| 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 |
|--|-----------------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| OXYQUINOLINE (UNII: 5UTX5635HP) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:13709-312-01 | 1 in 1 KIT | 04/22/2021 | |
| 1 | | 15 mL in 1 BOTTLE, DROPPER; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M014 | 04/22/2021 | |

Labeler - NEILMED PHARMACEUTICALS INC (799295915)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|----------------|---------------|----------------------------|
| NEILMED PHARMACEUTICALS INC | | 799295915 | manufacture(13709-312) |

Revised: 1/2024

NEILMED PHARMACEUTICALS INC