

**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

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