

SUAVEAR- suavear solution/ drops
NeilMed Pharmaceuticals Inc.

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.

SuavEar







Drug Facts

Active Ingredient	Purpose
Carbamide Peroxide 6.5%	Earwax removal aid

Uses 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
- 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 ear plugs 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 ear wax due to release of oxygen. There may be associated "crackling" sound
- Keep cap on bottle when not in use

Inactive Ingredients Glycerin, Oxquinoline

Do not use if package is tampered

MANUFACTURED BY 601 Aviation Blvd., Santa Rosa, CA 95403 USA

NeilMed PHARMACEUTICALS, INC.

1 (877) 477-8633

ISO 13485: 2012 International Accreditation
 Quality Management System Certified Company

MDSS GmbH Schiffgraben 41
 30175 Hannover, Germany

CE

NDC 13709-230-08

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2722-ENU-US-Rev4-PP20170707

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List of inactive ingredients

Glycerin, Oxyquinoline

Ear canal cleaning

For occasional aid to soften, loosen and remove excessive earwax

Purpose

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Keep out of reach of children.

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1 FREE TOOL
NeilMed®
EAR SPIN SAFE

DOCTOR DEVELOPED

- Soft
- Flexible
- Multi-Use

EAR CLEANING TOOL



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

FREE TOOL INCLUDED

• Complete 2-step system
 • Safely removes excessive earwax

Compare to active ingredient in Murine® Ear Wax Removal System*

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

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SUAVEAR

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-233
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:13709-233-01	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/09/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/09/2016	

Labeler - NeilMed Pharmaceuticals Inc. (783557783)**Establishment**

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals, Inc.		799295915	manufacture(13709-233)

Revised: 3/2016

NeilMed Pharmaceuticals Inc.