

**CLEARCANAL EAR WAX SOFTENER DROPS- carbamide peroxide 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.*

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**Drug Facts**

Drug Facts:

Active ingredient: CARBAMIDE PEROXIDE

**Ear Wax Removal Drops Directions**

Step 1 Ear Wax 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.
- Tip of applicator should not enter ear canal.
- Keep drops in ear for several minutes by keeping head tilted or placing enclosed ear plugs in ear.
- Use twice daily for upto 4 days if needed or as directed by a doctor.
- Any wax remaining after treatment may be removed by gently flushing the ear with NeilMed ClearCanal rinsing system with special ear rinse adapter.
- Children under 12 years of age: consult a doctor.

Avoid exposing bottle to excessive heat and direct sunlight. Keep cap on bottle when not in use.

Inactive Ingredients: Glycerin, Oxyquinoline, Aloe Barbadensis, Chamomile

Softens ear wax. Ear wax removal drops

Children under 12 years of age: consult a doctor.

Keep out of 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.

Do not use:

- \* If you have had an allergic reaction to Carbamide Peroxide.
- \* 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

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

When using this product:

- \* Avoid contact with the eyes

**Ear Wax Removal Complete System**

Ear wax is an important part of your body's system for keeping dirt, bacteria and other things from causing hearing problems. When rinsing is necessary, this cleaning system helps to soften, loosen and remove the excessive ear wax.

The system consists of kit with 1 bottle carbamide peroxide solution 15mL and 1 can sterile saline spray 177mL (or 125mL).

Place 5 to 10 drops of 6.5% carbamide peroxide solution into ear.

Warnings:

Do not use:

If you have had an allergic reaction to carbamide peroxide.

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:

void contact with the eyes

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

3" W x 1.375" H 0.125" CR

**⚠ WARNINGS:** Do not use and consult a doctor if you have excessive drainage or discharge, ear pain, irritation, rash in the ear or feel dizzy. Do not use if you have any perforation (hole) of the eardrum before or after ear surgery unless directed by a doctor. Do not use for more than two consecutive days. If excessive earwax remains after use of this product, consult a doctor.

**⚠ CAUTIONS:** Avoid exposing bottle to excessive heat and direct sunlight. Keep cap on bottle when not in use. Avoid contact with eyes. Keep this & all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center. Do not heat the bottle.

**📖 DIRECTIONS:** For use in the ear only. Adults and children over 12 years of age: Tilt head sideways and place 10 drops into each ear. Tip of applicator should not enter ear canal. Keep drops in the ear for 10 minutes by keeping your head tilted or use ear plugs. If needed, rinse ear after treatment by gently flushing the ear with **NeilMed® ClearCanal®** (supplied in a canister with a special ear rinse adapter) or any other commercial system recommended by your doctor. Use maximum twice per week if needed or as directed by a doctor. Children under 12 years of age: Consult a doctor.

**NOTE:** Ear Drops will foam on contact with earwax due to the release of oxygen.

**ACTIVE INGREDIENT:** Carbamide Peroxide 6.5%.

**INACTIVE INGREDIENT:** Glycerin and Oxyquinoline.

**NeilMed®**  
**clearcanal®**

**EARWAX  
SOFTENER  
DROPS**



**Pain Free  
Fast Acting  
Alcohol Free**

15 mL (0.5 fl oz)



MANUFACTURED FOR  
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Santa Rosa, CA 95403 USA

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NDC 13709-230-01  
6011-ENU-US\_REV14\_GP20181228\_kp

## CLEARCANAL EAR WAX SOFTENER DROPS

carbamide peroxide solution/ drops

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-230
Route of Administration	AURICULAR (OTIC)		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)				
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)				
ALOE (UNII: V5VD430YW9)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-230-01	1 in 1 BOX	01/02/2012	
1		15 mL in 1 BOTTLE, DROPPER; 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		08/24/2011	

**Labeler** - NeilMed Pharmaceuticals, Inc. (799295915)

## Establishment

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals, Inc.		799295915	manufacture(13709-230)

Revised: 4/2020

NeilMed Pharmaceuticals, Inc.