

## **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 e

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 ad 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  
**NeilMed**  
PHARMACEUTICALS, INC.

601 Aviation Blvd.,  
Santa Rosa, CA 95403 USA

Toll Free in USA & Canada  
1-877-477-8633

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NDC 13709-230-01

6011-ENU-US\_REV14\_GP20181228\_kp

# ClearCanal Earwax Removal Kit\_Product Label

**Drug Facts**  
**Active Ingredient(s)**  
Carbamide Peroxide 6.5%

**Purpose**  
Earwax Softener

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

**Warnings**  
Avoid using this product and seek a doctor before use if you have:  
• Ear pain, drainage or discharge  
• Impacted earwax  
• Ear infection, irritation or rash in the ear  
• A blocked Eustachian tube, dizziness, or vertigo  
• An injury or perforation (hole) of the eardrum  
• Tubes in the ear

• Had recent eye/skin/surgical  
• Had an allergic reaction to carbamide peroxide or other ingredients in this product in the past  
• Had diabetes, high blood pressure, thyroid disease or diabetes to prevent contact; do not share this product with others

**When using this product:**  
Avoid contact with the eyes. If accidental contact occurs, flush eyes with water for 15 minutes.  
Keep out of reach of children.  
• Consider severe reaction after use of this product  
• Not to use this product more than 3 times per week.  
Keep tube and all drops out of the reach of children.  
Children under 12 years should not use this product.  
For more information, get medical help or contact a Poison Control Center (1-800-232-1233) right away.

**Caution**  
**First Aid**  
Adults and children over 12 years of age:  
• If in head enclosure:  
• Place 10 drops into each ear  
• Tip of the earplug should not enter ear canal  
• Keep drops in the ear for ten minutes by keeping your head tilted or using earplugs.  
• Wash ears after treatment by gently flushing each ear with Neotimed® Earwax Removal Solution or lukewarm water.  
• Clean up to reduce ear wax, or as recommended by your physician.

**Other information:**  
• Store product in the outer carton, and do not discard carton or enclosed printed materials.  
• Product will form on contact with excess due to release of oxygen; there may be an immediate clumping agent.  
• Keep cap on bottle when not in use.  
• Contains 10 earplugs and 10 wax softening drops per bottle.  
Recommended storage conditions:  
• Store between 60°F and 80°F (15°C to 27°C). Product can temporarily be exposed to temperatures ranging from 41°F to 104°F (5°C to 40°C) during transportation.  
• Store out of sunlight, away from heat sources and avoid freezing.

**Contains Carbamide Peroxide**  
**Directions**  
• Use as directed.  
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**Directions:**  
This product is intended for use on adults and children over 12 years of age. Consult your physician for use on children under 12.

Tilt head sideways and place 10 drops of ClearCanal® carbamide peroxide into each ear canal by squeezing the plastic dropper bottle provided with this system. The tip of bottle should not enter ear canal.

Keep drops in ear for 10 minutes by keeping head tilted or placing enclosed ear plugs in ears. It is normal to feel warmth in ear due to carbamide peroxide.

Remove ear plugs. Attach the special drainage collection cup to the canister to avoid the rinse solution dripping out of your ear. Flush ears with the Neotimed® Earwax Removal Solution specially designed actuator nozzle for 10 seconds or as desired to achieve adequate flushing. Gently tilt head side to side to drain out residual liquid and dry ears with a clean dry towel wrapped on a finger.

On rare instances, individuals may experience pressure in the ears. If this occurs, stop rinsing. If symptoms persist please seek medical attention or contact Neotimed® directly.

Some users prefer to use the bulb syringe, so we are providing a silicone bulb syringe and a tip. The syringe is specially designed to easily pull apart for cleaning. Please use ONLY warm purified water at body temperature which is around 98.6°F or 37°C. All the components of the syringe can be cleaned with soap and a water and sterilized by placing in boiling water for five minutes.

**Dr. Mehta's Earwax Removal Complete Kit™**  
Earwax is important in preventing dirt and bacteria from causing hearing problems. If there is an excess of wax build up, ear rinsing may be necessary to soften, loosen and wash it out.

**NeilMed® ClearCanal®**  
*Dr. Mehta's*  
**Earwax Removal Complete Kit™**

Contains 5 complete treatments

Contains 1 soft silicone ear syringe 20 ml (2.0 fl. oz.), 1 bottle of ear drops 10 ml (0.5 fl. oz.), 1 drainage collection cup, 2 ear plugs, 1 ear wax softening tool and 1 soft silicone ear syringe. Colors of parts may vary.

**Dr. Mehta's Rule of 10™ Method for Earwax Removal**  
10 DROPS per ear  
plug ears for 10 MINUTES  
rinse each ear for 10 SECONDS

Please read complete directions before using product. Contains 5 complete treatments.

Also Available from Neotimed® SKI Separately

**NeilMed® WaxOut® Plus**  
12 COUNT

- WAX BUILD UP
- ITCHING
- EXFOLIATION
- WATER EXTRACTION

FOUR UNIQUE DESIGNS

## CLEARCANAL EAR WAX SOFTENER DROPS

carbamide peroxide solution/ drops

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13709-230
<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: PDC6A3C0OX)	
<b>OXYQUINOLINE</b> (UNII: 5UTX5635HP)	

**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		
2	NDC:13709-230-10	1 in 1 KIT	08/24/2012	
2		15 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

**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: 5/2021

NeilMed Pharmaceuticals, Inc.