

# **CLEARCANAL EAR WAX SOFTENER DROPS- carbamide peroxide solution/ drops**

**NeilMed Pharmaceuticals, Inc.**

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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

<p><b>⚠ WARNINGS:</b> 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.</p> <p><b>⚠ CAUTIONS:</b> Avoid exposing bottle to excessive heat and direct sunlight. Keep cap on bottle when not in use. Avoid contact with eyes. Keep this &amp; 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.</p>	<p><b>📖 DIRECTIONS:</b> 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 <b>NeilMed® ClearCanal®</b> (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.</p> <p><b>NOTE:</b> Ear Drops will foam on contact with earwax due to the release of oxygen.</p> <p><b>ACTIVE INGREDIENT:</b> Carbamide Peroxide 6.5%. <b>INACTIVE INGREDIENT:</b> Glycerin and Oxyquinoline.</p>	<p><b>NeilMed®</b> <b>clearcanal®</b></p> <p><b>EARWAX SOFTENER DROPS</b></p>  <p><b>Pain Free Fast Acting Alcohol Free</b></p> <p>15 mL (0.5 fl oz)</p>		
<p>MANUFACTURED FOR <b>NeilMed</b> PHARMACEUTICALS, INC.</p>	<p>601 Aviation Blvd., Santa Rosa, CA 95403 USA</p>	<p>Toll Free in USA &amp; Canada 1-877-477-8633</p>	<p>© <b>NeilMed®</b> 2000-2019 <a href="http://www.neilmed.com">www.neilmed.com</a></p>	<p>NDC 13709-230-01 6011-ENU-US_REV14_GP20181228_kp</p>

## ClearCanal Earwax Removal Kit\_Product Label

**Drug Facts**  
**Active Ingredient:**  
 Carbamide Peroxide 6.5%

**Purpose:**  
 Earwax Softener

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

**Warnings:**  
 Avoid using this product and ask a doctor before use if you have:  
 • Ear pain, drainage or discharge  
 • Itchy ear canal  
 • Ear infection, irritation or rash in the ear  
 • Meniere's Syndrome, dizziness, or vertigo  
 • An injury or perforation (hole) of the eardrum  
 • Tubes in the ear  
 • Had recent ear/sinus surgery  
 • Had an allergic reaction to carbamide peroxide or other ingredients in this product in the past  
 • Had a history of high blood pressure, thyroid disease or diabetes  
 To prevent contamination, do not share this product with others.

**How to use this product:**  
 Avoid contact with the eyes. If accidental contact occurs, flush eyes with water for 15 minutes.  
 Stop use and ask a doctor if:  
 • Irritation becomes more severe after use of this product  
 • You have been using this product more than twice per week  
 • Ringing and/or fullness in the ear persists after use of this product  
 • Children under 12 years should not use this product.  
 If swallowed, get medical help or contact a Poison Control Center (1-800-235-2223) right away.

**Caution:**  
 Keep out of the reach of children.  
 Adults and children over 12 years of age:  
 • Use 10 drops  
 • Place 10 drops into each ear  
 • Tip the application area to allow ear wax to soften  
 • Keep drops in the ear for ten minutes by keeping your head tilted or using earplugs  
 • Wipe away after treatment by gently flushing each ear with Acetic Acid (5%) or Mineral Oil (10%)  
 • Use up to twice per week, 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 foam on contact with water due to release of oxygen; there may be an associated stinging sensation.  
 • Keep cap on bottle tightly until use.  
 • Contents of container are for personal use; do not purchase or distribute to others.  
 • 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 131°F (5°C to 55°C) during transportation.  
 • Store out of sunlight, away from heat sources and avoid freezing.

**Keep out of reach of children.**

**Acetic Acid (5%)**  
 Dicyclohexyl Dimethyl Carbodiimide

**Ingredients:**  
 Carbamide Peroxide (6.5%)  
 USP Grade Water, USP Sodium Chloride (0.9%), USP Sodium Bicarbonate (0.1%), 1.0 mg/mL to 1.0 mg/mL pH.  
 No preservatives.

**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 ear canal to avoid the release solution dripping out of your ear. Flush ears with the **NeilMed® ClearCanal®** 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 **NeilMed®** 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 96.6° F or 37° C. All the components of the syringe can be cleaned with soap and 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™**

**SOFT SILICONE EAR SYRINGE**  
**WAX SOFTENING CARBAMIDE PEROXIDE**  
**2 SOFT EAR PLUGS**  
**DRAINAGE COLLECTION CUP**  
**WAXOUT™ TOOL**

**Contains 5 complete treatments**

Contents: 1 can sterile saline spray 70 ml (2.5 fl. oz.), 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.

**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 **NeilMed®** Soft Security

**NeilMed® WaxOut Plus**

**12 COUNT**

- WAX BUILD UP
- ITCHING
- EXFOLIATION
- WATER EXTRACTION

**FOUR UNIQUE DESIGNS**

MANUFACTURED BY:

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ISO 13485: 2016 International Accreditation Quality Management System Certified Company

US Pat. Nos. 8,238,180/743,254;  
 CAN Pat. Nos. 1,420,300/1,577,070; JP Pat. No. 14,920,002;  
 EU CTM Pat. Nos. 2104118-1/2104119-1/2104119-2

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NDC 13709-230-10

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 PPM20023-4p

# 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 Drug	M014	08/24/2011	

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

### Establishment

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

Revised: 1/2024

NeilMed Pharmaceuticals, Inc.