

**NEILMED CLEAR CANAL EARWAX REMOVAL KIT- carbamide peroxide solution/
drops
NEILMED PHARMACEUTICALS INC**

NeilMed ClearCanal EarWax Removal Complete Kit (BKC)

Drug Facts

Active Ingredients

Carbamide Peroxide 6.5%

Purpose

Earwax Softener

Uses

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

! Warnings

Avoid using the product and ask a doctor before use if you have :

- Ear pain, drainage or discharge
- Impacted earwax
- 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 ears
- Has recent ear/mastoid surgery
- Had an allergic reaction to carbamide peroxide or other ingredients in this product in the past.
- Heart disease, high blood pressure, thyroid disease or diabetes

To prevent contamination, do not share this product with others.

When using this product:

Avoid contact with the eyes. If accidental contact occurs, flush eyes with water and consult a doctor.

Stop use and ask a doctor if:

- Excessive earwax remains after use of this product
- You wish to use this product more than twice per week

Keep this and all drugs out of the reach of children

Children under 12 years should not use this product.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

FOR USE IN THE EAR ONLY

Adults and children over 12 years of age:

- Tilt head sideways
- Place 10 drops into each ear
- Tip of the applicator should not enter ear canal
- Keep drops in the ears for ten minutes by keeping your head tilted or using earplugs
- Rinse ears after treatment by gently flushing each ear with NeilMed® ClearCanal® spray or bulb syringe
- 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 earwax due to release of oxygen; there may be an associated crackling sound.
- Keep cap on bottle when not in use.
- Contents in canister are under pressure; do not puncture or incinerate

Recommended storage conditions:

- Store between 59°F and 86°F (15°C to 30°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

Inactive Ingredients

Glycerin, Oxyquinoline

Ingredients for ClearCanal® Saline Spray :

- USP Grade Water, USP Sodium Chloride (9mg/ml), USP Sodium Bicarbonate (0.4mg to 1.0mg/ml) to neutralize pH.
- Benzalkonium Chloride is added as a preservative

Contents :

1 can saline spray 75ml (2.53 fl oz), 1 bottle of ear drops 15ml (0.5 fl oz), 1 drainage collection cup, 2 ear plugs, 1 waxout tool and 1 soft silicone ear syringe. Colors of parts may vary.

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 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 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.

ClearCanal Earwax Removal Complete Kit

NeilMed
clearcanal
Dr. Mehta's
Earwax Removal Complete Kit™

Drug Facts

Active Ingredients
 Carbamide Peroxide 0.5%

Purpose
 Earwax Softener

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

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

When using this product
 Avoid contact with the eyes. If accidental contact occurs, flush eyes with water and consult a doctor.

Stop use and ask a doctor if:
 • Excessive earwax remains after use of this product
 • You wish to use this product more than twice per week

Keep kids and all drugs out of the reach of children.
 Children under 12 years should not use this product. If swallowed, get medical help or contact a Poison Control Center (1-800-232-1232) right away.

Directions
FOR USE IN THE EAR ONLY
 Adults and children over 12 years of age:
 • Tilt head sideways
 • Place 10 drops into each ear
 • Tip of the applicator should not enter ear canal
 • Keep drops in the ears for ten minutes by keeping your head tilted or using wedges
 • Rinse ears after treatment by gently flushing each ear with **NeilMed® clearcanal®** spray or bulb syringe
 • 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 earwax due to release of oxygen; there may be an associated crackling sound.
 • Keep cap on bottle when not in use.
 • Contents in carrier are under pressure; do not puncture or incise.
 • Recommended storage conditions: 30°C
 • Store between 59°F and 86°F (15°C to 30°C). Product can temporarily be exposed to temperatures ranging from -4°F to 131°F (-20°C to 55°C) during transportation.
 • Shroud of sunlight, away from heat sources and avoid freezing.

Inactive Ingredients
 Glycerin, Chondroitine

Ingredients for **NeilMed® Saline Spray:**
 • USP Grade Water, USP Sodium Chloride (0.9%), USP Sodium Bicarbonate (0.4 mg to 1.0 mg/mL), Benzalkonium Chloride (as a preservative).

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 carrier to avoid the rinse 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 soft medical grade silicone ear 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.

Important: Please do not discard this printed box and any enclosed printed material. The inside final product may not have all the details you require for the ongoing use of the product.



Dr. Mehta's Rule of 10™ Method for Earwax Removal

10 DROPS per ear
10 MINUTES plug ears for
10 SECONDS rinse each ear for

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

Also Available from NeilMed® Sold Separately

NeilMed
WaxOut Plus

12 COUNT

• WAX BUILD UP
 • ITCHING
 • EXFOLIATION
 • WATER EXTRACTION

FOUR UNIQUE DESIGNS

MANUFACTURED BY:
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 www.neilmed.com

MED-09151543-2916, Certified Company
 US Pat. Nos. 5,636,480/743,524; CAN Pat. Nos. 1470268/37790; JP Pat. No. 1476206; EU CTM Pat. Nos. 2154112-12154112-3

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ClearCanal Earwax Removal Saline Spray



NEILMED CLEAR CANAL EARWAX REMOVAL KIT

carbamide peroxide solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-314
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:13709-314-01	1 in 1 KIT	12/25/2021	
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 Drug	M014	12/25/2021	

Labeler - NEILMED PHARMACEUTICALS INC (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
NEILMED PHARMACEUTICALS INC		799295915	manufacture(13709-314)

Revised: 1/2024

NEILMED PHARMACEUTICALS INC