

**WAX OUT PLUS- carbamide peroxide drops solution/ drops**  
**NEILMED PHARMACEUTICALS INC**

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**Waxout Plus**

**Drug Facts Carbamide Peroxide drops**

**Active Ingredients**

Carbamide Peroxide 6.5%

**Purpose**

Earwax Removal Aid

**Uses**

Use occasionally as an aid to soften, loosen , and remove excessive earwax.

**Warnings**

Do not use:

- If you have had an allergic reaction to carbamide peroxide or other ingredients in the dropper bottle.
- If you have ear drainage or discharge, ear pain, ear infections, irritation, rash in the ear, or are dizzy. (Please consult a doctor with concerns).
- If you have an injury or perforation (hole) of the eardrum or after ear surgery or mastoid surgery, unless directed by a doctor.
- More than twice a week.
- For children under 12 years of age.
- If you have tubes in your ears.

**When using this product:**

- Avoid contact with eyes
- Keep out of reach of children
- If swallowed, get medical help or contact a poison control center immediately.
- If accidental contact with eyes occurs, flush eyes with water and consult a doctor.
- System is designed for a single user to reduce the risk of contamination. **DO NOT SHARE WITH OTHERS**
- **Individuals with Meniere's Syndrome or those experiencing dizziness, vertigo, impacted earwax or other ear problems should not use this product unless directed by a physician.**
- 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.

## **Other Information**

- Keep cap on plastic bottle when not in use.

## **Inactive Ingredients**

Glycerin, Oxyquinoline

## **Directions for ReUsable Ear Cleaners**

For use in the ear only. Make sure to check physical integrity of the tool prior to use. When using for the first time, begin with the COIL tool. Grasp tool comfortably between thumb, index and middle fingers. Direct toward ear. Gently advance tool toward the ear canal and SPIN tool continuously - slowly advancing into the outer portion of canal. Rotate in one direction per insertion. For additional extraction, try the BRISTLE, SCREW or CLUB tools. DO NOT POKE OR JAB INTO EAR. DO NOT FORCIBLY ADVANCE. NOT FOR DEEP CANAL INSERTION. Each person's requirements vary. Impacted earwax should be removed by a health care professional. Check with your physician.

### **DISINFECTIONS INSTRUCTIONS:**

Clean with soap and warm water followed by immersing eartools in isopropyl rubbing alcohol 70%. Use tool when dry.

### **SUGGESTED USE:**

Intended for EAR HYGIENE: Cleaning of debris, itch relief, exfoliation, water extraction and superficial wax around the ear and outer ear canal. Daily or less frequent use may be beneficial.

## **Directions for Dosing**

- To aid with the softening of the earwax, you may use NeilMed Clear Canal Earwax Softener in conjunction with the eartools to provide maximum benefit.
- Remove the cap from the NeilMed Clear Canal EarWax Softener bottle and squeeze a few drops of the solution into the cavity of the cap. Dip the tip of the ear tool into the solution so that the tip of the tool is coated with softener solution. Follow the directions given for use of the tools.
- Wash the cap with warm water and dry completely before placing back on softener bottle
- If you wish, you may also place 10 drops of NeilMed Clear Canal Earwax Softener in the ear canals as directed prior to use of the eartools. Keep ear plugged for 5-10 minutes. Now use the tools to remove the softened earwax.

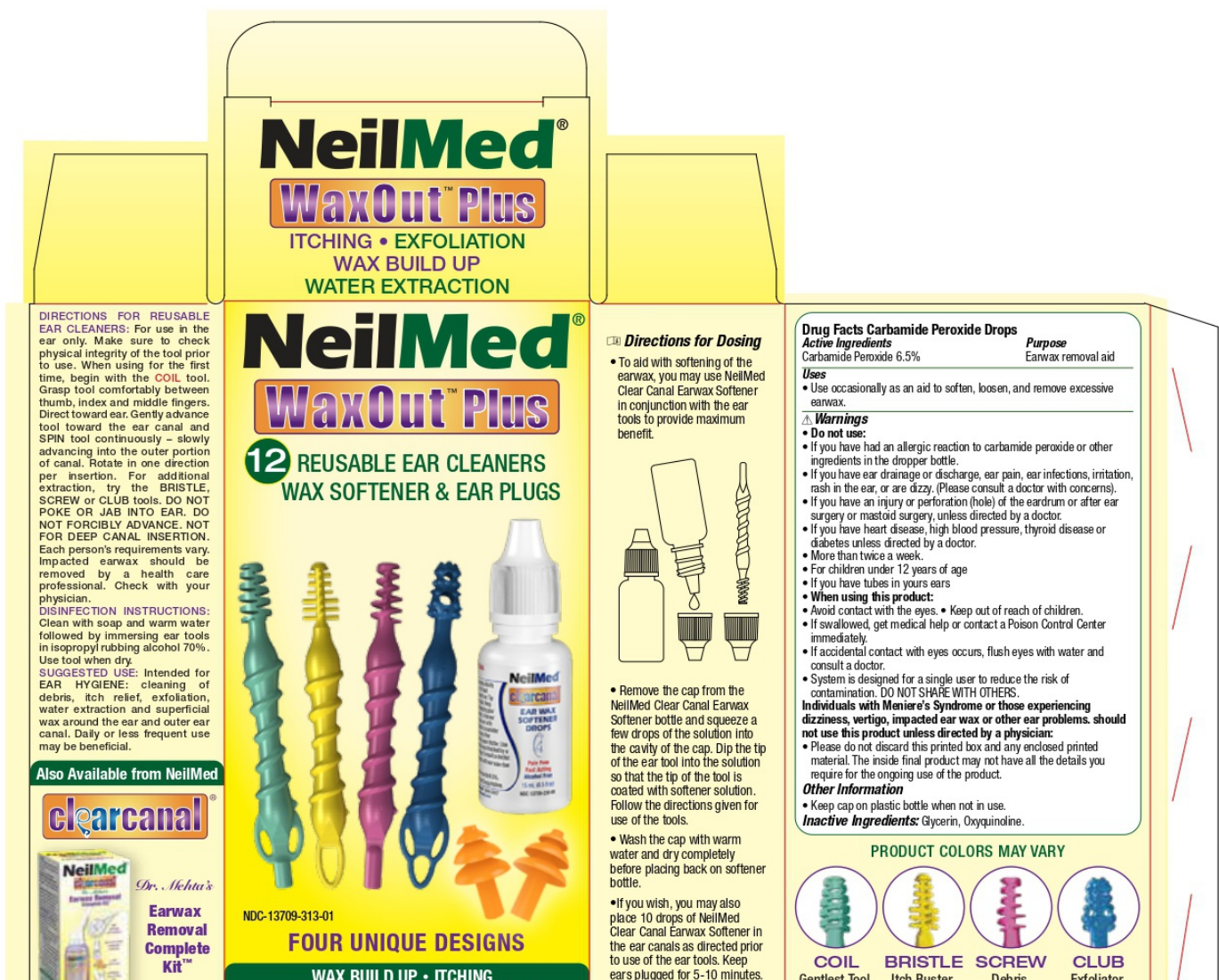
## **when Using this product**

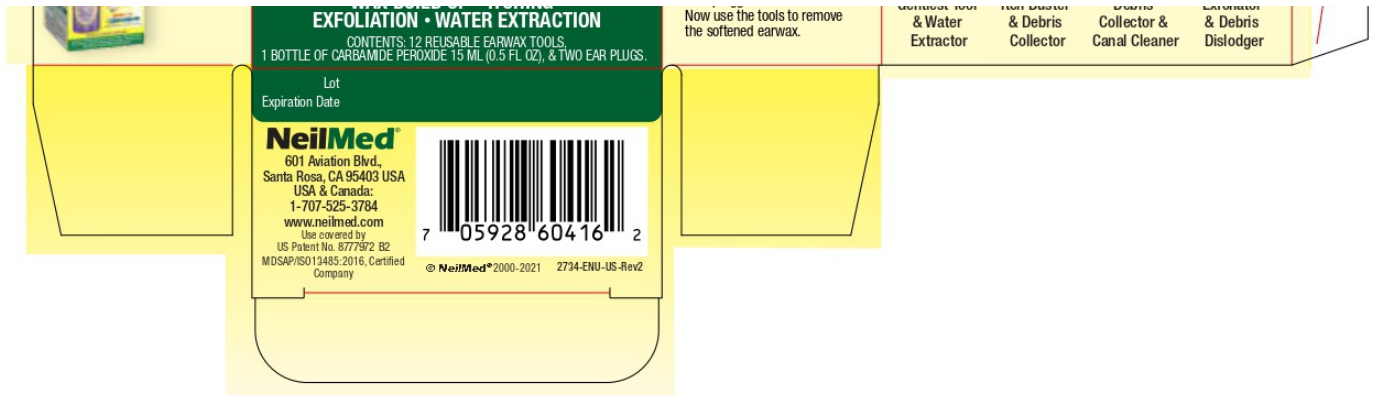
Keep out of reach of Children

## **Warnings :**

### **Do not use:**

If you have tubes in your ears.





## WAX OUT PLUS

carbamide peroxide drops solution/ drops

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-313
Route of Administration	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>OXYQUINOLINE</b> (UNII: 5UTX5635HP)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-313-01	1 in 1 KIT	10/01/2019	
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	11/05/2018	

**Labeler** - NEILMED PHARMACEUTICALS INC (799295915)

## Establishment

Name	Address	ID/FEI	Business Operations
NEILMED PHARMACEUTICALS INC		799295915	manufacture(13709-313)

Revised: 1/2024

NEILMED PHARMACEUTICALS INC