

**EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid  
Randob Labs, Ltd.**

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**ERO Earwax Removal Kit**

FOR USE IN THE EAR ONLY

**Adults & Children over 12 yrs of age:**

Tilt head to the side and place 5-10 drops into ear.

Dropper tip of removal drops should not enter ear canal.

Keep drops in ear for several minutes by keeping head tilted or placing cotton in the ear.

Use twice daily for up to four days if needed, or as directed by a doctor.

Safely scoop out wax with removal tool.

Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using the ear bulb syringe.

**Children under 12 yrs of age:**

Consult a doctor.

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

Earwax Removal Aid

Carbamide Peroxide 6.5%

Aloe Barbadensis Leaf Extract

Chamomilla Recutita (Matricaria) Flower Extract

Glycerin

Mineral Oil

Oxyquinoline Sulfate

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center (1-800-222-1212) right away.

**When using this product** avoid contact with eyes.

**Stop use and ask a doctor if:**

you need to use more than four days

excessive earwax remains after use of this product

**Other Information**

Do not use if neck wrap imprinted safety seal is broken or missing

Do not store above 25 degrees C, 77 degrees F

Store bottle in outer carton

Keep cap on bottle when not in use

Product foams on contact with earwax due to release of oxygen

## Warnings

### Ask a doctor before use if you have:

ear drainage or discharge

ear pain

irritation, or rash in the ear

dizziness

an injury or perforation (hole) of the eardrum

recently had ear surgery

**DO NOT USE IF TAMPER EVIDENT SHRINK FILM IS BROKEN OR MISSING.**

**Ask a doctor before use if you have:** • ear drainage or discharge • ear pain • irritation or rash in the ear • dizziness • an injury or perforation (hole) of the eardrum • recently had ear surgery. **When using this product** avoid contact with the eyes. **Stop use and ask a doctor if:** • you need to use for more than four days • excessive earwax remains after use of this product. **Keep out of reach of children.** If swallowed, get medical help or contact a poison control center (1-800-222-1222) right away. **CAUTIONS:** Dropper tip of removal drops should not enter ear canal. When rinsing the ear with warm water, the tip of the syringe should not obstruct the flow of water leaving the ear canal. This product is not intended to restore hearing loss due to medical reasons. In such cases, consult a doctor.

**ER•O**  
BY RANDO• LABS, LTD.

**EARWAX  
REMOVAL  
DROPS**

with Chamomile & Aloe

Safe, Fast-Acting  
Doctor-Recommended  
Alcohol-Free

**0.5 FL OZ (15 ml)**

**NOTE:** ERO Earwax Removal Drops will foam on contact with earwax due to release of oxygen.

**ACTIVE INGREDIENT:** Carbamide Peroxide 6.5%

**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. Dropper tip of removal drops should not enter ear canal. Keep drops in ear for several minutes by keeping head tilted or placing cotton in ear. Use twice daily for up to four days if needed, or as directed by a doctor. Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using the ear bulb syringe. Children under 12 years of age: consult a doctor. Do not store above 25° C, 77° F.

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PN 875B

**EARWAX REMOVAL KIT**  
Carbamide Peroxide 6.5%

**ERO**  
BY RANDOEB LABS, LTD.

Safe and Fast-Acting  
Doctor-Recommended

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**Drug Facts**

<b>Active Ingredient</b> Carbamide Peroxide 6.5%	<b>Purpose</b> Ear wax removal aid
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**Uses** For occasional use as an aid to soften, loosen and remove excessive earwax.

**Warnings**  
Ask a doctor before use if you have ear drainage or discharge, ear pain, irritation or rash in the ear, dizziness, an injury or perforation (hole) of the eardrum, recently had ear surgery.

**When using this product** avoid contact with the eyes.

**Stop use and ask a doctor if:** you need to use for more than four days; excessive earwax remains after use of this product.

**Keep out of reach of children.** 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 and place 5 to 10 drops into ear • Dropper tip of removal drops should not enter ear canal • Keep drops in ear for several minutes by keeping head tilted or placing cotton in ear • Use twice daily for up to four days if needed, or as directed by a doctor • Slightly scoop out wax with removal tool • Any wax remaining after treatment may be removed by gently flushing the ear with warm water, using the ear bulb syringe • Children under 12 years of age: consult a doctor.

**Other information** • Do not use if neck wrap in printed safety seal is broken or missing • Do not store above 25° C, 77° F • Store bottle in the outer carton • Keep cap on bottle when not in use • Product foams on contact with earwax due to release of oxygen.

**Inactive ingredients** Aloe Barbadensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Glycerin, Mineral Oil, Oxyquinoline Sulfate.


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PN 878A

**ERO**  
BY RANDOEB LABS, LTD.

**EARWAX REMOVAL KIT**  
Carbamide Peroxide 6.5%  
with Soothing Chamomile & Aloe

*The Complete 3-PART SYSTEM*



**Drops, Ear Bulb Syringe and  
Wax Removal Tool with Safety Shield**

0.5 FL OZ (15 ML) DROPS, SYRINGE & REMOVAL TOOL

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**CAUTIONS:** Dropper tip of removal drops should not enter ear canal. ONLY the earwax removal tool should be used to remove earwax from the ear canal. Never use instruments such as cotton swabs, toothpicks, or hairpins to remove wax from the ear canal. When rinsing the ear with warm water, the tip of the syringe should not obstruct the flow of water leaving the ear canal.

**Earwax removal tool directions:** Wash tool before initial use with warm, soapy water. Rise and allow to dry completely before using. Repeat between uses. Grasp handle. Gently insert flex tip into ear canal. Sweep and rotate to engage wax. Remove wax and repeat.

**NOTE:** Do not use in abnormal ear canals. Do not use if pain occurs. Discard if cracked or broken. Use only as directed.


**WARNINGS:** Product contains small parts that pose a choking hazard. Keep out of reach of children.

For adult use only—not intended for use in children.

This product is not intended to restore hearing loss due to medical reasons. In such cases, consult a doctor.


**FDA-APPROVED USES:** For occasional use as an aid to soften, loosen and remove excessive earwax.

**A MORE COMPLETE CLEAN**  
Get rid of excess wax—easy as 1,2,3




1

**TREAT:** Tilt head and put 5-10 earwax removal drops in ear, wait a few minutes



2

**CLEAR:** Safely scoop out wax with removal tool





3

**CLEANSE:** Gently rinse with warm water using ear bulb syringe

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KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL INGESTION, SEEK PROFESSIONAL ASSISTANCE OR CONTACT POISON CONTROL CENTER IMMEDIATELY.





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VOID COATING

## EARWAX REMOVAL DROPS

carbamide peroxide 6.5% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52412-600
<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	0.065 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>OXYQUINOLINE SULFATE</b> (UNII: 61VUG75Y3P)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-600-05	1 in 1 CARTON	07/03/2020	
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	07/03/2020	

**Labeler** - Randob Labs, Ltd. (061995007)

**Registrant** - Pharma Nobis, LLC (118564114)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(52412-600) , analysis(52412-600) , label(52412-600) , pack(52412-600)

Revised: 12/2023

Randob Labs, Ltd.