

**FRESKARO EARWAX REMOVAL AID- carbamide peroxide 6.50% kit liquid**  
**Pharma Nobis, LLC**

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**Freskaro Earwax Removal Kit**

Carbamide Peroxide 6.5% non USP\*

\*pH differs from USP specifications

Earwax removal aid

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

**Do not use**

- 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 ear or after ear surgery, unless directed by a doctor
- for more than 4 consecutive days. If excessive earwax remains after use of this product, consult a doctor.

**When using this product**

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

**Stop use and ask a doctor if**

- excessive earwax remains after use of this product for 4 consecutive days.

Citric acid

Flavor

Glycerin

Propylene Glycol

Sodium Lauroyl Sarcosinate

Sodium Stannate

Purified Water

- **FOR USE IN THE EAR ONLY.** Remove any hearing aids before use.
- **Adults and children over 12 years of age:**
- tilt head sideways
- 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 cotton in the 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 ear with warm

(body temperature) water, using a soft rubber bulb ear syringe

- **Children under 12 years of age:** Consult a physician

If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts	
<b>Active ingredient</b>	<b>Purpose</b>
Carbamide peroxide 6.5% non USP* ...Earwax removal aid *pH differs from USP specifications	
<b>Use</b> For occasional use as an aid to soften, loosen and remove excessive earwax.	
<b>Warnings</b>	
<b>Do not use</b> ■ 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 ear or after ear surgery, unless directed by a doctor ■ for more than 4 consecutive days. If excessive earwax remains after use of this product, consult a doctor.	
<b>When using this product</b> ■ avoid contact with the eyes. If accidental contact with eyes occurs, flush eyes with water and consult a doctor.	
<b>Stop use and ask a doctor if</b> ■ excessive earwax remains after use of this product for 4 consecutive days.	
<b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<b>FOR USE IN THE EAR ONLY.</b> Remove any hearing aids before use.	
<b>Adults and children over 12 yrs of age:</b> tilt head sideways and place 5 to 10 drops into the ear. Tip of applicator 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 4 days if needed, or as directed by a doctor. ■ Any wax remaining after the 4-day treatment may be removed by gently flushing the ear with warm (body temperature) water, using a soft rubber bulb ear syringe. <b>Children under 12 yrs of age:</b> Consult a physician. <i>Continued</i> ▶	

**Drug Facts (continued)**

**Other information**  
 ■ do not store above 25°C (77°F) ■ store bottle in outer carton ■ product foams contact with earwax due to the release of oxygen. There may be an associated "crackling" sound keep cap on bottle when not in use

**Inactive ingredients**  
 Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sarcosinate, Sodium Stannate, Purified Water

**Questions & comments?**  
 1-833-351-0932

**IMPORTANT**  
 Keep this carton for future reference on full labeling.

\* This product is not manufactured or distributed by Prestige Brands Inc., owner of the registered trademark Debrox® Ear Drops.

Manufactured by:  
 Pharma Nobis  
 7400 Alumax Dr,  
 Texarkana, TX 75501  
 R080125  
 009790420

**Freskáro**  
 refresh & revitalize


**Earwax Removal Aid**  
 Carbamide Peroxide, 6.5%

**Freskáro**  
 refresh & revitalize

**COMPARE TO Debrox® Ear Drops**  
 active ingredient\*

NDC 82645-097-90

**Earwax Removal Aid**  
 Carbamide Peroxide, 6.5%



- Safe & Gentle Foaming
- Cleansing Action

**0.5 fl. oz (15 mL)**

SEALED FOR YOUR PROTECTION. DO NOT USE IF SHRINK BAND ON BOTTLE IS BROKEN OR MISSING AT TIME OF PURCHASE.



3 82645 09790 5



# Ear Drops

Carbamide Peroxide,  
6.5%

## Earwax Removal Aid

- Safe & Gentle Foaming
- Cleansing Action

0.5 fl. oz (15 mL)

DO NOT USE IF SHRINK BAND ON BOTTLE IS BROKEN OR MISSING

<b>Drug Facts</b>	<b>Purpose</b> Carbamide peroxide 6.5% non USP* .....Earwax removal aid *pH differs from USP specifications
<b>Active Ingredient</b> Carbamide peroxide 6.5% non USP* .....Earwax removal aid *pH differs from USP specifications	
<b>Use</b> For occasional use as an aid to soften, loosen and remove excessive earwax	
<b>Warnings</b> Do not use ■ 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 ear or after ear surgery, unless directed by a doctor ■ for more than 4 consecutive days. If excessive earwax remains after use of this product, consult a doctor. When using this product ■ avoid contact with the eyes. If accidental contact with eyes occurs, flush eyes with water and consult a doctor. <b>Stop use and ask a doctor if</b> ■ excessive earwax remains after use of this product for 4 consecutive days. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions FOR USE IN THE EAR ONLY.</b> Remove any hearing aids before use. Adults and children over 12 yrs of age: tilt head sideways and place 5 to 10 drops into the ear. Tip of applicator 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 4 days if needed, or as directed by a doctor. ■ Any wax remaining after the 4-day treatment may be removed by gently flushing the ear with warm (body temperature) water, using a soft rubber bulb ear syringe. Children under 12 yrs of age: Consult a physician.	
<b>Other Information</b> Protect from heat and direct sunlight. Keep cap on bottle when not in use.	
<b>Inactive Ingredients</b> citric acid, flavor, glycerin, propylene glycol, sodium lauroyl sarcosinate, sodium stannate, purified water	
<b>Questions &amp; comments?</b> 1-833-551-0932	

Manufactured by: Pharma Nobis  
7400 Alুমax Dr., Texarkana, TX 75501  
009790420  
R080125

## FRESKARO EARWAX REMOVAL AID

carbamide peroxide 6.50% kit liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82645-097
<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	6.5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SODIUM STANNATE</b> (UNII: NJ7C1V83KG)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82645-097-90	1 in 1 CARTON	04/13/2026	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a		

Combination Product			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M014	04/13/2026	

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

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	pack(82645-097) , label(82645-097) , manufacture(82645-097) , analysis(82645-097)

Revised: 4/2026

Pharma Nobis, LLC