

**EAR DROPS- carbamide peroxide 6.5% liquid**  
**Bionpharma Inc.**

-----  
**ear drops**

***Active ingredients***

Carbamide Peroxide 6.5% non USP\*

\*pH differs from USP specifications

***Purposes***

Earwax removal aid

***Uses***

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

***Warnings***

**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 eyes

Stop use and ask a doctor

- you need to use for more than four days
- excessive earwax remains after a four day treatment with this product

**Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

**FOR USE IN THE EAR ONLY**

Remove any earing aids before use

**Adults and children over 12 yrs of age:** tilt head to the side and place 10 drops into the ear.

- Tip of applicator should not enter into the ear canal

- Keep drops in ear for several minutes by keeping head tilted sideways 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 treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe.

**Children under 12 yrs of age:** Consult a physician.

***Other information***

- do not store above 77°F (25°C)
- store bottle in outer carton
- product foams on contact with ear wax 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 Lauroyl Sarcosinate, Sodium Stannate, Purified Water.

***Questions & comments?***

call toll free 1-888-235-2466  
(Mon - Fri 9AM - 5PM EST)

a+health™

**ear drops  
carbamide  
peroxide 6.5%**

**earwax  
removal aid**

**SEALED FOR YOUR**

**PROTECTION.**

**DO NOT USE IF**

**SHRINKBAND**

**ON BOTTLE IS**

**BROKEN OR MISSING**

**AT TIME OF**

**PURCHASE.**

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

DISTRIBUTED BY:  
**Bionpharma Inc.**, Princeton, NJ 08540

L0000592

R0422

**Carton labeling**

**\*compare to the active ingredient  
in Debrox® Ear Drops**

**twin pack**

**a+health™**

**ear drops**

**carbamide**

**peroxide 6.5%**

**earwax removal aid**

**safe, gentle, non-irritating**

**easily cleanses ear with**

**microfoam action**

**1 fl oz (30mL)**

**two bottles 0.5 fl oz (15 mL) each**



## EAR DROPS

carbamide peroxide 6.5% liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69452-377
<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>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SODIUM STANNATE</b> (UNII: NJ7C1V83KG)	

<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69452-377-95	2 in 1 CARTON	09/15/2022	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:69452-377-75	1 in 1 CARTON	09/15/2022	
2		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	09/15/2022	

**Labeler** - Bionpharma Inc. (079637826)

**Registrant** - Bionpharma Inc. (079637826)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	manufacture(69452-377) , pack(69452-377)

Revised: 12/2024

Bionpharma Inc.