

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

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**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 earring 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)	

### Packaging

#	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		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M014	09/15/2022	

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

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

### Establishment

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

Revised: 9/2022

Bionpharma Inc.