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 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 was 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			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69452-377
Route of Administration	AURICULAR (OTIC)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CARBAMIDE PEROXIDE (UNII: 31PZ2VAU81) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	CARBAMIDE PEROXIDE	0.065 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM STANNATE (UNII: NJ7C1V83KG)	

SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (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		
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		

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: 1/2023 Bionpharma Inc.