

**EAR DROPS (CARBAMIDE PEROXIDE 6.5%) MAJOR- carbamide peroxide
6.5% liquid
NuCare Pharmaceuticals, 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.

Ear Drops Major

Carbamide Peroxide 6.5%

Earwax Removal Aid

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

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

When using this product avoid contact with eyes

Stop and ask doctor before use if • you need to use for more than four days • excessive earwax remains after use of this product

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 the children

If product is swallowed, get medical help or contact a Poison Control Center 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
 - 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 treatment may be removed by gently flushing the ear with warm water, using a soft rubber bulb ear syringe
- Children under 12 years of age: consult a doctor.

Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauroyl Sarcosinate, Sodium Stannate, Water

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

NuCare Pharmaceuticals, Inc.

NDC: 68071-2568-5

Ear Drops

15mL Drops

Carbamide Peroxide 6.5%

See manufacturer's label
for full list of ingredients.

Ear Drops

Lot: 00000

NDC: 68071-2568-05

MFR NDC: 0904-6627-35 Exp.: 00-00

Serial# 0000000002

Ear Drops

Lot: 00000

NDC: 68071-2568-05

MFR NDC: 0904-6627-35 Exp.: 00-00

Serial# 0000000002



GTIN 00368071256857

Serial# 0000000002

Exp. Date 00-00

LOT#: 00000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Product #: R0258015

Distributed by: 3 68071 25685 7
Major Pharmaceuticals Livonia, MI 48152
Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

EAR DROPS (CARBAMIDE PEROXIDE 6.5%) MAJOR

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2568(NDC:0904-6627)
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	6.5 g in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2568-5	1 in 1 CARTON	11/15/2021	
1		15 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part344	10/10/2019	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2568)

Revised: 11/2021

NuCare Pharmaceuticals, Inc.