

EAR DROPS MAJOR- carbamide peroxide 6.5% liquid
Major Pharmaceuticals

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.

MAJOR

NDC 0904-6627-35

Ear Drops

Carbamide Peroxide

6.5%

Non USP*

Earwax removal aid

- Safe, gentle, and non-irritating
- Easily cleans ear with foaming action

0.5 FL OZ (15 mL)

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

Drug Facts	Purpose
Active ingredient Carbamide peroxide 6.5% non USP* Earwax removal aid *pH differs from USP specifications	
Use For occasional use as an aid to soften, loosen and remove excessive earwax.	
Warnings Ask a doctor before use if you have ■ ear drainage or discharge ■ ear pain, irritation, or rash in the ear ■ recently had ear surgery ■ dizziness ■ an injury or perforation (hole) of the eardrum When using this product avoid contact with the eyes Stop use and ask a doctor if ■ you need to use for more than four days ■ excessive earwax remains after a four day treatment with this product Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center 1-800-222-1222 immediately. Directions FOR USE IN THE EAR ONLY. Remove any hearing aids before use. Adults and children over 12 yrs of age: tilt head to the side and place 5 to 10 drops into the ear canal. ■ 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. Inactive ingredients Citric Acid, Flavor, Glycerin, Propylene Glycol, Sodium Lauryl Sarcosinate, Sodium Stannate, Purified Water Questions or Comments? (800) 616-2471 RETAIN OUTER CARTON FOR FULL LABELING.	

Distributed by: MAJOR® PHARMACEUTICALS

17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152

Rev. 12/19 M-74 Re-order No. 701038

NDC 0904-6627-35

MAJOR

EAR DROPS

Carbamide Peroxide 6.5%

EARWAX REMOVAL AID

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Distributed by: MAJOR® PHARMACEUTICALS R120718

17177 N Laurel Park Drive, Suite 233, Livonia, MI 48152

Rev. 12/18 M-74 Re-order No. 701038

EAR DROPS MAJOR

carbamide peroxide 6.5% liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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
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SODIUM STANNATE (UNII: NJ7C1V83KG)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
WATER (UNII: 059QF0KOOR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6627-35	1 in 1 CARTON	10/10/2019	
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 - Major Pharmaceuticals (191427277)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(0904-6627) , manufacture(0904-6627) , pack(0904-6627) , label(0904-6627)

Revised: 3/2022

Major Pharmaceuticals