

EAR DROPS MAJOR- carbamide peroxide 6.5% liquid **Major Pharmaceuticals**

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%

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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 Drug	M014	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: 12/2023

Major Pharmaceuticals