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 \mathbb{I} you need to use for more than four days \bullet 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

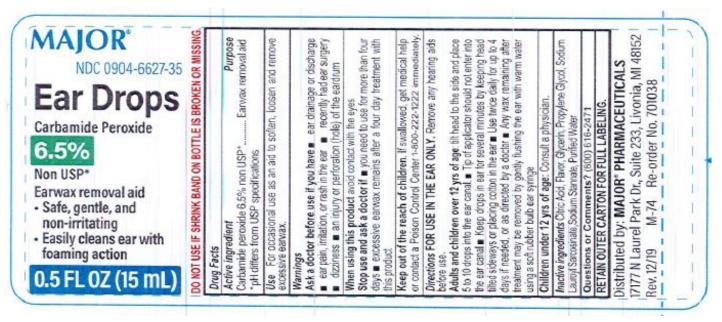
Directions- For use in the ear only.

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.



NDC 0904-6627-35

MAJOR° **EAR DROPS**

Carbamide Peroxide 6.5%

EARWAX REMOVAL AID

- · Safe, gentle & non-irritating
- with foaming action See Factive ingredient

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For occasional use as an aid to soften, loosen and remove EXCRESSIVE BATWAX.

Earwax removal aid

Carbamide peroxide 6.5%

Ask a doctor before use if you have a ear drainage or discharge a ear pain, intation, or rash in the ear a recently had ear surgery

rections FOR USE IN THE EAR ONLY, Remove any hearing aids

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

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		Ingredient Name	Basis of Strength	Strength
	CARBAMIDE PERO XIDE (UNII UNII:BBX060 AN9 V)	I: 31PZ2VAU81) (HYDROC		6.5 g in 100 mL

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

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:0904-6627-35	1 in 1 CARTON	10/10/2019		
	1	15 mL in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Infor	mation		
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 - Humco Holding Group, Inc. (825672844)

Establishment			
Name	Address		Business Operations
Humco Holding Group, Inc.		825672884	analysis (0904-6627) , manufacture (0904-6627) , pack (0904-6627) , label (0904-6627)

Revised: 12/2019 Major Pharmaceuticals