# **EARWAX REMOVAL DROPS- carbamide peroxide 6.5% liquid Humco Holding Group, Inc**

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### **Private Label Earwax Removal- 0097**

Citric Acid

Flavor

Glycerin

Propylene Glycol

Sodium Lauroyl Sarcosinate

Sodium Stannate

Purified Water

Earwax removal aid.

Adults and children over 12 yrs of age: tilt head to the side and place 5 to 10 drops into the ear canal.

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

For External Use Only.

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 eadrum

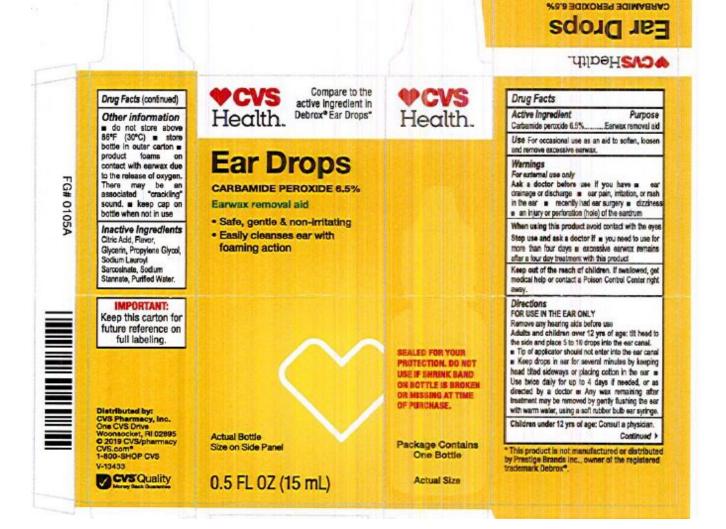
Carbamide Peroxide 6.5%

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

#### **CVS Label**

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sinto, Soline Saresa, Purfac Nase; eminoral use as an aid in refer, lossen and strong substance Removal Kit CARBAMIDE PEROXIDE 6.5% CVSHealth. Earwax The CVS Health "Environ Removal Kit, when used as directed, dearness the ear with fearing action to provide a safe, nor-infating method of settering and nemoving earwest. Distributed by: OVS Pharmacy, Inc., One OVS Drive, Woorsocker, Rt 12885 O 2019 CNS-pharmacy OVS.com\* 1-600-5910P DNS Note: Ear drops will foam on contact with earwax due to the release of oxygen. Ocvs Quality "This product is not constitution of or discriptions by Provides Drawtic Inc., wetter of the registered transmission (prints)." IMPORTANT: Keep this carton for future reference on full labeling. Actual Street Kit includes soft rubber bulb ear syringe & drops 1 RUBBER BULB SYRINGE & DROPS 0.5 FL 0Z (15 mL) Easily cleanses our with fearning action Safe, gentle & non-irritating CARBAMIDE PEROXIDE 6.5% Earwax removal aid Removal Kit ♥CVSHeαlth. Opened to Lether to Page? Earwax **♥CVS**Health. PACE VE VEN
POTETION SO NOT
PO One Bottle Actual State

Earwax removal aid



**EBIWARK removal aid** 

Leader Label



Carbamide Peroxide, 6.5% Earway: Removal Ald Removal Kit **E9LM9X** 

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#### Drug Facts

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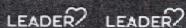
Describes & comments? 1-860-863-3435

The earway removal kit when used as clinicited, cleanings the sar with forming action to help soften and remove earway.

Note: ear disps will form in contact with sarway due to the mease of oneyer which may buse an associated clacking saund.

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Reford Size Intigator



### Earwax Removal Kit

Carbamide Peroxide, 5.5% Earwax Removal Aid

Earwax Removal Aid

Safe & Gentle

Foaming Cleansing Action

Kit Includes Soft Rubber Bulb Far Syringe & Drops

COMPARE TO DEBROX EAR DROPS sc. valingred e-T

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Reduced to



Rite Aid Label

CHRBHMIDE PEROXIDE 6.5%

### REMOVAL KIT **EARWAX**

DO NOT USE IF TAMPER EVIDENT SHRINKBAND ON BOTTLE IS BROKEN OR MISSING.

Drug Facts Use as use as an ext to softer, began sed the

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When using this product a solid contact with the eyes, if accidents contact with eyes copiers, but eyes with water and contact in decision.

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Other information Protect from heat and direct surlight sep cap on botto when such sure.

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**ACTUAL SIZE** 



"This product is not manufactured or distributed by Prestige Brands Inc., owner of the registered trademark.









### **BEMOVAL** KIT **EARWAX**

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Drug Facts	100
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DROPS BASY TO APPLY



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# EARWAX REMOVAL KIT

CARBAMIDE PEROXIDE 6.5%



# EARWAX REMOVAL KIT



REDUCED TO 60%





**Major Label** 

## MAJOR Ear Drops

Carbamide Peroxide 5.5% Non USP\*

Drug Facts

Active Ingredient Purpose Certamole perceide 6.5% con USP\* ... Euro "pH differs from USP specifications de 6.0% non USP\*.... Earwax re

Use For occasional use as an aid to soften, losser and remove excessive earway.

Warnings

For external use only.

Ask a doctor before use if you have a set dranage or discharge a set pair, initiation, or rosh in the ear a recently lade or suppry a "Extense a en injury or periodition (hole) of the earthum

When using this product avoid centact with the eyes

Stop Lies and ask a doctor if a you need to use for more than four days if excessive carwax remains after a four day treatment with this product

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center 1-809-222-1222 immediately.

Directions FOR USE IN THE EAR ONLY

Remove any hearing side before uso
Adults and chillionen over 12 yrs of age: tit.
head in the side and place 5 to 13 draps into the ear need as the side and stace 5 to 10 draps into the ear cases. In Tip of application should not enter into the ear cases. If Keep draps is ear for several minutes by keeping tread littles sideways or placing cotton is the ear. Use twice daily thrup to 4 days if needed, or as directed by a doctor. If Any was remaining other treatment may be removed by gendly flushing the ear with warm water, using a soft rubber butt ear syringe.

Children under 12 yrs of age: Consut a shedder. Confinant b

This product is not manufactured or distributed by Prestige Brands Inc., owner of the registered trademark Debroof.

This item does NOT contain CA Prop 65 ingredients.

Drug Fects (continued) Other information

 do not store above 86°F (30°C) store bottle in outer

 product foams on carried with carriers due to the ralease of coygen. There may be an associated keep cap on bottle when not in use

Inactive Ingredients Clarc Acid, Flavor, Glycenia: Propylene Glycol, Sodium Lauroyl Saxcoeinate, Sodium

Starrate, Purified Water,

Quastions or 800 615-2471

IMPORTANT

Keep his carton for future reference on full labeling.

Distributed by: MAJOR<sup>4</sup> PHARMACEUTICALS 17177 Ni Laurel Para Dr. Suite 233 Livonia Mi 48162

Rev. 12/19 M-74 Re-order No. 701036

MAJOR® NOC USBN 4655-35

Compare to active ingredient in Debrox Eas 3raps\*1

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 0Z (15 mL)

SEALED FOR YOUR PROTECTION. DO NOT USE IF ON BOTTLEIS BROKEN OR MISSING AT TIME OF



### **EARWAX REMOVAL DROPS**

carbamide peroxide 6.5% liquid

#### **Product Information**

**Product Type HUMAN OTC DRUG** Item Code (Source) NDC:0395-9133

AURICULAR (OTIC) **Route of Administration** 

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CARBAMIDE PEROXIDE (UNII: 31PZ 2VAU81) (HYDROGEN PEROXIDE - UNII: BBX060AN9V)	CARBAMIDE PEROXIDE	0.065 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		

SODIUM STANNATE (UNII: NJ7C1V83KG)	
SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

P	Packaging				
#	Item Code	Package Description Marketing Start Date		Marketing End Date	
1	NDC:0395- 9133-90	1 in 1 CARTON	06/04/2019		
1		15 mL in 1 CONTAINER; Type 0: Not a Combination Product			
2	NDC:0395- 9133-45	1 in 1 CARTON	06/04/2019		
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 Drug	M014	06/04/2019	

# Labeler - Humco Holding Group, Inc (825672884)

### Registrant - Pharma Nobis, LLC (118564114)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharma Nobis, LLC		118564114	manufacture(0395-9133), analysis(0395-9133), pack(0395-9133), label(0395-9133)	

Revised: 12/2023 Humco Holding Group, Inc